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# Drug Information Update

June 2018



## TABLE OF CONTENTS

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|   |    |
|---|----|
| NEWLY AVAILABLE GENERICS .....                    | 2  |
| NEW DRUG ENTITIES/COMBINATIONS/STRENGTHS .....    | 3  |
| NEW INDICATIONS (EXISTING DRUGS).....             | 5  |
| FDA NEWS/BULLETINS/ADVISORIES/SAFETY ALERTS ..... | 8  |
| STUDIES AND RECENT TOPICS.....                    | 13 |
| RECALLS .....                                     | 17 |
| CURRENT DRUG SHORTAGES.....                       | 52 |

**NEWLY AVAILABLE GENERICS**

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| GENERIC DRUG NAME              | STRENGTH & DOSAGE FORM | GENERIC MANUFACTURER | BRAND NAME |
|--------------------------------|------------------------|----------------------|------------|
| OXYCODONE<br>HCL/ACETAMINOPHEN | 2.5mg-300mg            | FORTE BIO-PHARM      | NALOCET    |

## NEW DRUG ENTITIES/COMBINATIONS/STRENGTHS

| DESCRIPTION  | BRAND NAME                     | GENERIC NAME                   | STRENGTH                | NOTES                        |
|--|--------------------------------|--------------------------------|-------------------------|------------------------------|
| SKELETAL MUSCLE RELAXANTS                          | BACLOFEN                       | BACLOFEN                       | 5MG                     | New Strength                 |
| EYE ANTIBIOTIC, GLUCO-CORTICOID AND NSAID COMB     | DEXAMETHASONE-MOXIFLOX-KETORLC | MOXIFLOX/DEXAMET/KETOR/NACL/PF | 0.5-1-.4/1              | New Combination              |
| EYE ANTIINFLAMMATORY AGENTS                        | DEXYCU                         | DEXAMETHASONE/PF               | 9 %                     | New Route and Dosage Form    |
| ANTIVIRALS, HIVSPECIFIC, PROTEASE INHIBITORS       | NORVIR                         | RITONAVIR                      | 100 MG                  | New Dosage Form              |
| ANTIPARKINSONISM DRUGS, OTHER                      | OSMOLEX ER                     | AMANTADINE HCL                 | 129 MG                  | New Strength and Dosage Form |
| ANTIPARKINSONISM DRUGS, OTHER                      | OSMOLEX ER                     | AMANTADINE HCL                 | 193 MG                  | New Strength and Dosage Form |
| ANTIPARKINSONISM DRUGS, OTHER                      | OSMOLEX ER                     | AMANTADINE HCL                 | 258 MG                  | New Strength and Dosage Form |
| ANTIMIGRAINE PREPARATIONS                          | AIMOVIG AUTOINJECTOR           | ERENUMAB-AOOE                  | 70MG/ML                 | New Entity                   |
| ANTIMIGRAINE PREPARATIONS                          | AIMOVIG AUTOINJECTOR (2 PACK)  | ERENUMAB-AOOE                  | 70MG/ML                 | New Entity                   |
| ANTISEBORRHEIC AGENTS                              | ESKATA                         | HYDROGEN PEROXIDE              | 40%                     | New Strength                 |
| PANCREATIC ENZYMES                                 | ZENPEP                         | LIPASE/PROTEASE/AMYLAASE       | 3-10-14K                | New Strength                 |
| TRICYCLIC ANTIDEPRESSANTS,REL.NO N-SEL.REUPT-INHIB | NORTRIPTYLINE HCL              | NORTRIPTYLINE HCL              | 20MG/10ML Oral Solution | Unit Dose                    |
| NOSE PREPARATIONS, MISCELLANEOUS (RX)              | GOPRELTO                       | COCAINE HCL                    | 4 %                     | New Route                    |
| EYE ANTIBIOTIC AND GLUCOCORTICOID COMBINATIONS     | TRIAMCINOLONE-MOXIFLOXACIN     | TRIAMCINOLON/MOXIFLOX/WATER/PF | 9-0.6MG/.6              | New Combination              |
| GLUCOCORTICIODS, ORALLY INHALED                    | ARNUITY ELLIPTA                | FLUTICASONE FUROATE            | 50 MCG                  | New Strength                 |
| THROMBOPOIETIN RECEPTOR AGONISTS                   | DOPTELET                       | AVATROMBOPAG MALEATE           | 20 MG                   | New Entity                   |

| DESCRIPTION  | BRAND NAME | GENERIC NAME                    | STRENGTH                 | NOTES           |
|--|------------|---------------------------------|--------------------------|-----------------|
| ANTINEOPLASTIC - ANTIANDROGENIC AGENTS             | YONSA      | ABIRATERONE ACET, SUBMICRONIZED | 125 MG                   | New Entity      |
| ANTINEOPLASTIC - ANTIANDROGENIC AGENTS             | GILENYA    | FINGOLIMOD HCL                  | 0.25 MG                  | New Strength    |
| NARCOTIC WITHDRAWAL THERAPY AGENTS                 | LUCEMYRA   | LOFEXIDINE HCL                  | 0.18 MG                  | New Entity      |
| JANUS KINASE (JAK) INHIBITORS                      | OLUMIANT   | BARICITINIB                     | 2 MG                     | New Entity      |
| ERYTHROPOIESIS-STIMULATING AGENTS                  | RETACRIT   | EPOETIN ALFA-EPBX               | 2000/ML Vial             | New Entity      |
| ERYTHROPOIESIS-STIMULATING AGENTS                  | RETACRIT   | EPOETIN ALFA-EPBX               | 10000/ML Vial            | New Entity      |
| ERYTHROPOIESIS-STIMULATING AGENTS                  | RETACRIT   | EPOETIN ALFA-EPBX               | 3000/ML Vial             | New Entity      |
| ERYTHROPOIESIS-STIMULATING AGENTS                  | RETACRIT   | EPOETIN ALFA-EPBX               | 4000/ML Vial             | New Entity      |
| PKU TREATMENT AGENTS - PHENYLALANINE AMMONIA LYASE | PALYNZIQ   | PEGVALIASE-PQPZ                 | 2.5 MG/0.5 Syringe       | New Entity      |
| PKU TREATMENT AGENTS - PHENYLALANINE AMMONIA LYASE | PALYNZIQ   | PEGVALIASE-PQPZ                 | 10MG/0.5ML Syringe       | New Entity      |
| PKU TREATMENT AGENTS - PHENYLALANINE AMMONIA LYASE | PALYNZIQ   | PEGVALIASE-PQPZ                 | 20 MG/ML Syringe         | New Entity      |
| INTERLEUKIN-6 (IL-6) RECEPTOR INHIBITORS           | KEVZARA    | SARILUMAB                       | 200MG/1.14 Pen Injection | New Dosage Form |
| INTERLEUKIN-6 (IL-6) RECEPTOR INHIBITORS           | KEVZARA    | SARILUMAB                       | 150MG/1.14 Pen Injection | New Dosage Form |

## NEW INDICATIONS (EXISTING DRUGS)

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### Prolia®

**May 21, 2018**

THOUSAND OAKS, Calif./PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced that the U.S. Food and Drug Administration (FDA) has approved the use of Prolia® (denosumab) for the treatment of glucocorticoid-induced osteoporosis (GIOP) in men and women at high risk of fracture, defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy. This approval is based on data from a Phase 3 study which showed patients on glucocorticoid therapy who received Prolia had greater gains in bone mineral density (BMD) compared to those who received active comparator (risedronate).

Source: Amgen

### Arnuity® Ellipta®

**May 21, 2018**

GSK today announced it has received approval from the US Food and Drug Administration (FDA) for the use of Arnuity Ellipta (fluticasone furoate) a once-daily inhaled corticosteroid (ICS) medicine for the maintenance treatment of asthma in children from as young as 5 years. This makes Arnuity one of the few once-daily treatments for asthma licensed in the US in this younger age group, where there remains a significant need for convenient and effective treatment options.

Source: GSK

### AVASTIN®

**June 13, 2018**

Genentech, a member of the Roche Group (SIX: RO, ROG; OTCQX: RHHBY), today announced that the U.S. Food and Drug Administration (FDA) has approved Avastin® (bevacizumab) in combination with chemotherapy (carboplatin and paclitaxel), followed by Avastin as a single agent, for the treatment of women with advanced (stage III or IV) ovarian cancer following initial surgical resection.

Source: Genentech

### KEYTRUDA®

**June 13, 2018**

KENILWORTH, N.J.--(BUSINESS WIRE)--Merck (NYSE:MRK), known as MSD outside the United States and Canada, today announced that the U.S. Food and Drug Administration (FDA) has approved KEYTRUDA®, the company's anti-PD-1 therapy, for the treatment of adult and pediatric patients with refractory primary mediastinal large B-cell lymphoma (PMBCL), or who have relapsed after two or more prior lines of therapy. This indication is approved under the FDA's accelerated approval regulations based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials. KEYTRUDA is not recommended for the treatment of patients with PMBCL who require urgent cytoreductive therapy. With this indication, KEYTRUDA becomes the first anti-PD-1 therapy to be approved for the treatment of PMBCL, a type of non-Hodgkin lymphoma. This is the second indication for KEYTRUDA for the treatment of a hematologic malignancy.

Source: Merck

## Venclexta®

**June 8, 2018**

Genentech, a member of the Roche Group (SIX: RO, ROG; OTCQX: RHHBY), announced today that the U.S. Food and Drug Administration (FDA) has approved Venclexta® (venetoclax) in combination with Rituxan® (rituximab) for the treatment of people with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL), with or without 17p deletion, who have received at least one prior therapy. Venclexta is being developed by AbbVie and Genentech, a member of the Roche Group. It is jointly commercialized by the companies in the United States and commercialized by AbbVie outside of the United States.

Source: Genentech

## Rituxan®

**June 7, 2018**

Genentech, a member of the Roche Group (SIX: RO, ROG; OTCQX: RHHBY), today announced that the U.S. Food and Drug Administration (FDA) has approved Rituxan® (rituximab) for the treatment of adults with moderate to severe pemphigus vulgaris (PV), a rare, serious, potentially life threatening condition characterized by progressive painful blistering of the skin and mucous membranes.

Source: Genentech

## MIRCERA®

**June 7, 2018**

The Food and Drug Administration approved methoxy polyethylene glycol-epoetin beta (Mircera, Vifor Pharma Inc.) for the treatment of pediatric patients 5 to 17 years of age on hemodialysis who are converting from another ESA after their hemoglobin level was stabilized with an ESA. Approval was based on data from an open-label, multiple dose, multicenter, dose-finding trial (NCT00717366) in 64 pediatric patients (ages 5 to 17 years) with CKD on hemodialysis and had stable hemoglobin (Hb) levels while previously receiving another ESA (epoetin alfa/beta or darbepoetin alfa). Patients were administered Mircera intravenously once every 4 weeks for 20 weeks. After the first administration of Mircera, dosage adjustments were permitted to maintain target Hb levels.

Source: U.S. Food and Drug Administration (FDA)

## XELJANZ®

**May 30, 2018**

Pfizer Inc. (NYSE: PFE) announced today that the United States (U.S.) Food and Drug Administration (FDA) approved XELJANZ® (tofacitinib) 10 mg twice-daily (BID) for at least eight weeks, followed by XELJANZ 5 mg BID or 10 mg BID, for the treatment of adult patients in the U.S. with moderately to severely active ulcerative colitis (UC).

Source: Pfizer Inc.

## CIMZIA®

**May 28, 2018**

Brussels, Belgium –07:00 CEST – UCB announced today that the U.S. Food and Drug Administration (FDA) has approved extending the label for CIMZIA® (certolizumab pegol) to include a new indication in adults with moderate-to-severe plaque psoriasis. CIMZIA is indicated for the treatment



of adults with moderate-to-severe plaque psoriasis (PsO) who are candidates for systemic therapy or phototherapy. The approval makes CIMZIA the first Fc-free, PEGylated anti-TNF treatment option for this indication and marks the entry of UCB into immuno-dermatology, where significant unmet need currently exists. The approval also follows a recent FDA label update for CIMZIA in pregnancy and breastfeeding that provides essential information to healthcare professionals and women.

Source: UCB



## FDA NEWS/BULLETINS/ADVISORIES/SAFETY ALERTS

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### [Juluca, Tivicay, Triumeq \(dolutegravir\): FDA to Evaluate - Potential Risk of Neural Tube Birth Defects](#) [Posted 05/18/2018]

**ISSUE:** Serious cases of neural tube birth defects involving the brain, spine, and spinal cord have been reported in babies born to women treated with dolutegravir used to treat human immunodeficiency virus (HIV). Preliminary results from an ongoing observational study in Botswana found that women who received dolutegravir at the time of becoming pregnant or early in the first trimester appear to be at higher risk for these defects.

Neural tube defects are birth defects that can occur early in pregnancy when the spinal cord, brain, and related structures do not form properly. To date, in this observational study there are no reported cases of babies born with neural tube defects to women starting dolutegravir later in pregnancy. We are investigating this new safety issue and will update the public when we have more information.

**BACKGROUND:** Dolutegravir is an FDA-approved antiretroviral medicine used in combination with other antiretroviral medicines to treat HIV, the virus that can cause acquired immunodeficiency syndrome (AIDS). Dolutegravir works by blocking integrase, an HIV enzyme, to prevent the virus from multiplying and can reduce the amount of HIV in the body. Stopping dolutegravir without first talking to a prescriber can cause the HIV infection to become worse. Approved in 2013, dolutegravir has been on the market for 5 years, and is available as a single ingredient product under the brand name Tivicay and as a fixed dose combination tablet with other HIV medicines under the brand names Juluca and Triumeq.

**RECOMMENDATION:** Patients should not stop taking dolutegravir without first talking to your health care professional because stopping your medicine can cause the HIV infection to worsen.

Source: U.S. Food and Drug Administration (FDA)

### [Keytruda \(pembrolizumab\) or Tecentriq \(atezolizumab\): FDA Alerts Health Care Professionals and Investigators: FDA Statement - Decreased Survival in Some Patients in Clinical Trials Associated with Monotherapy](#) [Posted 05/18/2018]

**ISSUE:** FDA is alerting health care professionals, oncology clinical investigators, and the public about decreased survival associated with the use of Keytruda (pembrolizumab) or Tecentriq (atezolizumab) as single therapy (monotherapy) in clinical trials to treat patients with metastatic urothelial cancer who have not received prior therapy and who have low expression of the protein programmed death ligand 1 (PDL1).

In two ongoing clinical trials (KEYNOTE-361 and IMVIGOR-130), the Data Monitoring Committees' (DMC) early reviews found patients in the monotherapy arms of both trials with PD-L1 low status had decreased survival compared to patients who received cisplatin- or carboplatin-based chemotherapy.

Health care professionals should be aware that the populations enrolled in the ongoing clinical trials were eligible for platinum-containing chemotherapy, and therefore differ from those enrolled in the trials that led to the accelerated approvals of both Keytruda and Tecentriq in the treatment of patients

with locally advanced or metastatic urothelial carcinoma who are not eligible for cisplatin-containing chemotherapy.

**BACKGROUND:** Both Keytruda and Tecentriq are currently approved under accelerated approval for the treatment of locally advanced or metastatic urothelial carcinoma patients who are not eligible for cisplatin containing chemotherapy, irrespective of PD-L1 status. Keytruda and Tecentriq are also currently approved by the FDA for the treatment of multiple types of other cancers.

**RECOMMENDATION:** Patients should talk to their doctor if they have questions or concerns about either drug. Patients taking Keytruda or Tecentriq for other approved uses should continue to take their medication as directed by their health care professional.

Source: U.S. Food and Drug Administration (FDA)

## Homeopathic Teething Drops, Nausea Drops, Intestinal Colic Drops, Stomach Calm, Expectorant Cough Syrup, Silver-Zinc Throat Spray, and Argentum Elixir by MBI Distributing: Recall - Due to a Lack of Adequate Controls

[Posted 05/21/2018]

**ISSUE:** MBI Distributing, Inc. is voluntarily recalling all lots of homeopathic Teething Drops, Nausea Drops, Intestinal Colic Drops, Stomach Calm, Expectorant Cough Syrup, Silver-Zinc Throat Spray, and Argentum Elixir, within expiry, to the consumer level. The drug products have been found to be manufactured with a lack of adequate controls.

Manufacturing products without proper process controls increases the probability that products will vary in strength, quality and purity. Use of these products could result in an adverse reaction, especially in vulnerable populations such as infants and children. To date, MBI Distributing, Inc. has not received any reports of adverse events related to this recall.

**BACKGROUND:** These homeopathic drug products are in liquid oral dosage form and are packaged in sizes from 1 fluid ounce to 8 fluid ounces.

**RECOMMENDATION:** MBI Distributing, Inc. is notifying its distributors and retailers by mail and is arranging for return of all recalled drug products in their possession. Consumers who have recalled product in their possession should stop using and discard the recalled product.

Source: U.S. Food and Drug Administration (FDA)

## Oral Over-the-Counter Benzocaine Products: Drug Safety Communication - Risk of Serious and Potentially Fatal Blood Disorder

[Posted 05/23/2018]

**ISSUE:** The FDA is warning that over-the-counter (OTC) oral drug products containing benzocaine should not be used to treat infants and children younger than 2 years. We are also warning that benzocaine oral drug products should only be used in adults and children 2 years and older if they contain certain warnings on the drug label. These products carry serious risks and provide little to no benefits for treating oral pain, including sore gums in infants due to teething. Benzocaine, a local anesthetic, can

cause a condition in which the amount of oxygen carried through the blood is greatly reduced. This condition, called methemoglobinemia, can be life-threatening and result in death. Due to the significant safety risk of methemoglobinemia, we have urged manufacturers that they should stop marketing OTC oral drug products for treating teething in infants and children younger than 2 years. If companies do not comply, we will take action to remove these products from the market.

We have also urged manufacturers of OTC oral drug products containing benzocaine for adults and children 2 years and older to make the following changes to the labels of their products:

Adding a warning about methemoglobinemia;

Adding contraindications, FDA's strongest warnings, directing parents and caregivers not to use the product for teething and not to use in infants and children younger than 2 years; and

Revising the directions to direct parents and caregivers not to use the product in infants and children younger than 2 years.

**BACKGROUND:** Benzocaine is a local anesthetic contained in some OTC products for the temporary relief of pain due to minor irritation, soreness, or injury of the mouth and throat. Benzocaine products are marketed as gels, sprays, ointments, solutions, and lozenges under brand names such as Anbesol, Orabase, Orajel, Baby Orajel, Hurracaine, and Topex, as well as store brands and generics. Prescription local anesthetics include articaine, bupivacaine, chloroprocaine, lidocaine, mepivacaine, prilocaine, ropivacaine, and tetracaine.

**RECOMMENDATION:** We continue to monitor the safety and effectiveness of OTC benzocaine products and intend to take additional actions in the future as needed. We will notify the public about any updates. In addition to our recent actions regarding OTC benzocaine products, we are also requiring a standardized methemoglobinemia warning to be included in the prescribing information of all prescription local anesthetics.

Source: U.S. Food and Drug Administration (FDA)

## **TAYTULLA (norethindrone acetate and ethinyl estradiol capsules and ferrous fumarate capsules) by Allergan: Recall - Due to Out of Sequence Capsules** **[Posted 05/29/2018]**

**ISSUE:** Allergan recently identified, through a physician report, that four placebo capsules were placed out of order in a sample pack of TAYTULLA and the first four days of therapy had four non-hormonal placebo capsules instead of active capsules.

As a result of this packaging error, oral contraceptive capsules, that are taken out of sequence, may place the user at risk for contraceptive failure and unintended pregnancy. The reversing of the order may not be apparent to either new users or previous users of the product, increasing the likelihood of taking the capsules out of order.

**BACKGROUND:** This product is an oral contraceptive indicated for the prevention of pregnancy in women who elect to use oral contraceptives. The TAYTULLA pill pack is a 28 count blister card that has 24 "active" pink softgel capsules (with hormones) with "WC" printed on the outer shell in white to be

taken for 24 days, followed by 4 maroon softgel capsules (without hormones) also imprinted with “WC” on one side to be taken for the next four days.

**RECOMMENDATION:** Patients who have the sample pack product with the lot #5620706 Exp. May 2019, should notify their healthcare provider to arrange a return or if they have questions. Patients with questions regarding this recall can contact Allergan by phone at 800-678-1605 8am-8pm EST Monday through Friday.

**Apotex Corp. Issues Voluntary Nationwide Recall of Fluticasone Propionate Nasal Spray USP 50 mcg Per Spray 120 Metered Sprays Due to Potential for Small Glass Particles**  
**[Posted 05/31/2018]**

**ISSUE:** The Fluticasone Propionate Nasal Spray 50 mcg per spray 120 Metered Sprays has been found to contain small glass particles. The glass particles could block the actuator and impact the functionality of the pump. The issue was discovered through a customer complaint. There is a potential for patients to be exposed to the glass particles and mechanical irritation cannot be ruled out. Local trauma to the nasal mucosa might occur with use of the defective product. To date, Apotex Corp. has not received any reports of adverse events related to recall.

**BACKGROUND:** Fluticasone Propionate Nasal Spray is indicated for the treatment of seasonal and perennial allergic rhinitis and for the management of sinus pain and pressure associated with allergic rhinitis in patients 4 to 17 years of age.

**RECOMMENDATION:** Patients, wholesalers, retailers, hospitals or institutions with Lot# NJ4501 and an expiration date of July 2020, should stop use and distribution of the remaining units and quarantine immediately. Healthcare Professionals in your organization should be informed of this recall.

Source: U.S. Food and Drug Administration (FDA)

**Naloxone Hydrochloride Injection, USP, 0.4 mg/mL, 1 mL in 2.5 mL in the Carpuject™ Singleuse Cartridge Syringe System by Hospira: Recall - Due to the Potential Presence of Particulate Matter**  
**[Posted 06/04/2018]**

**ISSUE:** Hospira, Inc., a Pfizer company, is voluntarily recalling lots 72680LL and 76510LL of Naloxone Hydrochloride Injection, USP, 0.4 mg/mL, 1 mL in 2.5 mL, Carpuject Single-use cartridge syringe system (NDC 0409-1782-69), to the hospital/institution level due to the potential presence of embedded and loose particulate matter on the syringe plunger.

In the event that impacted product is administered to a patient, the patient has a low likelihood of experiencing adverse events ranging from local irritation, allergic reactions, phlebitis, end-organ granuloma, tissue ischemia, pulmonary emboli, pulmonary dysfunction, pulmonary infarction, and toxicity. To date, Hospira, Inc. has not received reports of any adverse events associated with this issue for these lots.



**BACKGROUND:** Naloxone Hydrochloride, an opioid antagonist, is indicated for the complete or partial reversal of opioid depression. It is also indicated for the diagnosis of known or suspected opioid overdose, and as an adjunctive agent for the management of septic shock.

**RECOMMENDATION:** Distributors or retailers with an existing inventory of the lots, which are being recalled, should stop use and distribution and quarantine immediately. Inform Healthcare Professionals in your organization of this recall. If you have further distributed the recalled product, to the wholesale or retail level, please notify any accounts or additional locations which may have received the recalled product from you. For additional assistance, call Stericycle at 1-800-805-3093 between the hours of 8 a.m. to 5 p.m. ET, Monday through Friday.

Source: U.S. Food and Drug Administration (FDA)

## STUDIES AND RECENT TOPICS

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### FDA floats end to 'confusing and inefficient' drug-device process

May 16, 2018

The FDA is proposing to eliminate a mechanism for reconsidering the regulatory classification of combination products. Officials put the process on the chopping block after determining it is confusing, inefficient and unlikely to lead to the original decision being overturned.

Source: [fiercebiotech.com](http://fiercebiotech.com)

### Regulators flag possible birth defect link to GSK's HIV drug

May 18, 2018

U.S. and European regulators said they were assessing evidence that GlaxoSmithKline's HIV drug dolutegravir might be linked to serious birth defects, casting a shadow over a medicine that has been a key profit driver in recent years.

Source: [reuters.com](http://reuters.com)

### Banned Pregnancy Drug Linked to ADHD Generations Later

May 21, 2018

A pregnancy drug that has been banned for decades may increase the risk for attention-deficit/hyperactivity disorder (ADHD) generations later, new research suggests. The study found that the grandchildren of women who took a synthetic estrogen, diethylstilbestrol (also known as DES), to prevent pregnancy complications between 1938 and 1971, are more likely to have the disorder.

Source: [healthday.com](http://healthday.com)

### FDA issues warning letters to companies selling kratom products

May 22, 2018

The U.S. Food and Drug Administration said on Tuesday it issued warning letters to three companies that illegally marketed and distributed products containing the substance, kratom, which they claimed treat opioid addiction and withdrawal.

Source: [reuters.com](http://reuters.com)

### Pain: Virpax's Tony Mack says spray-on drugs a better way than opioids, patches

May 29, 2018

Malvern-based Virpax Pharmaceuticals says it has licensed MedPharm Ltd. "to develop non-opioid pain management products delivered" through Virpax's "'Patch-in-a-Can' MedSpray" system. Virpax has acquired the rights to several skin-based non-opioid painkiller drug-delivery systems and is developing drugs including DSF100 (NSAID spray film 1.3 percent), which the company says should allow for "long-term dosing" through the skin or mucous membranes from a spray can, and an anesthetic system that can be delivered through a liposomal gel.

Source: philly.com

## **Marijuana: a green grey zone for patients, doctors, and pharma companies** **May 30, 2018**

If you live in one of the 20 states where marijuana is legal but only for medical use, access to the drug begins at the doctor's office. But unlike most other treatments, it is not granted via a prescription pad. That's because marijuana remains a schedule 1 substance. (Physicians can only write prescriptions for schedule 2 drugs or higher.) This classification encapsulates a wider paradox: marijuana is defined as a drug with no medical value and a high potential for abuse by the federal government, but it is now legal for medical use in most states. Once dismissed as a drug for slackers, marijuana has entered the mainstream so completely it's been embraced by wellness enthusiasts. Sixty-one percent of Americans support its legalization.

Source: mmm-online.com

## **Severe Folate Deficiency Associated With Olaparib for Relapsed Ovarian Cancer** **May 31, 2018**

Patients receiving olaparib (Lynparza) for relapsed ovarian cancer (OC) may develop folate deficiency, according to findings of a small case series from researchers at Rush University Medical Center in Chicago. The researchers discovered severe folate deficiency in a patient receiving olaparib, a poly (ADP-ribose) polymerase (PARP)-inhibitor, for relapsed ovarian cancer with no plausible explanation for the adverse effect. To their knowledge, this is the first case indicating an association between olaparib therapy and folate deficiency.

Source: oncologynurseadvisor.com

## **Study finds rare gain for tough-to-treat pancreatic cancer** **June 4, 2018**

Patients with pancreatic cancer that hadn't spread lived substantially longer on a four-drug combo than on a single standard cancer drug, a rare advance for a tough-to-treat disease, researchers reported Monday. The results indicate the powerful chemotherapy treatment known as folfinox will likely become standard of care for the minority of patients whose pancreatic cancer is diagnosed early enough to be removed by surgery, experts not involved in the study said.

Source: apnews.com

## **This Fungus Could Help Cure Cancer** **June 4, 2018**

Maureen Hillenmeyer doesn't know exactly what's growing in her incubators, but she has high hopes. The rectangular plates in the backroom of Hexagon Bio are heated to 86F and filled with yeasts unlike any other. The fungal microorganisms have been painstakingly outfitted with custom-printed DNA parts that give ordinary baker's yeast the capacity to make new compounds that could potentially cure disease. "When we know it's making a molecule, then we go in and say, 'Is that molecule doing



something interesting to cancer cells?’ ” says Hillenmeyer, co-founder and chief executive officer of Hexagon, based in Menlo Park, Calif. “That’s the real field testing.”

Source: bloomberg.com

## FDA clears insulin management system

**June 6, 2018**

The FDA granted 510(k) clearance for the Omnipod DASH Insulin Management System, a tubeless insulin pump system that wirelessly connects to a bolus calculator and two smartphone apps for diabetes management, Insulet announced in a press release.

Source: healio.com

## Bezafibrate Normalizes Liver Enzymes in PBC

**June 6, 2018**

A lipid-lowering drug also works in primary biliary cholangitis (PBC) to normalize biochemical liver measures, researchers found. Among patients randomized to 24 months of bezafibrate therapy on top of ursodeoxycholic acid, 31% had a complete biochemical response -- in the form of normal levels of total bilirubin, alkaline phosphatase, aminotransferases, and albumin, as well as a normal prothrombin index -- in contrast to the zero patients who achieved this on ursodeoxycholic acid alone (P<0.001), according Christophe Corpechot, MD, of Saint-Antoine University Hospital in Paris, and colleagues.

Source: medpagetoday.com

## How An Old Diabetes Drug Made A Big Splash At The Biggest Cancer Confab

**June 7, 2018**

At the recently concluded annual meeting of the American Society of Clinical Oncology (ASCO) a group of researchers from Mexico City described a surprising discovery: In a phase 2 trial in patients with stage 4 lung cancer, a 24-year-old diabetes drug significantly improved survival when added to a standard therapy. That drug, metformin, is used to lower blood sugar in type 2 diabetics. And because it went generic years ago, it generally costs pennies a pill—an advantage that’s enticing to the oncology community, which has been grappling with questions about how to pay for new and very expensive therapies like mutation-targeting and checkpoint-blocking drugs.

Source: forbes.com

## Nuplazid’s Risks in Treating Parkinson’s Psychosis Don’t Appear Exceptionally High, Experts Say

**June 11, 2018**

The controversy surrounding Nuplazid (pimavanserin), Acadia Pharmaceuticals’ approved treatment for psychosis in Parkinson’s patients, has made its way to scientific journals. But experts appear to take a more questioning view of the medication’s risks than that aired by general media.

Source: parkinsonsnewstoday.com





**Why prescription drug shortages are so costly**  
**June 13, 2018**

President Donald Trump's proposed blueprint to lower prescription drug prices has prompted plenty of speculation about the reasons behind America's outsized medicine costs. In all the analysis, however, one expensive and dangerous piece of the equation may be overlooked: chronic drug shortages.

Source: [cbsnews.com](http://cbsnews.com)

## RECALLS

| Product Type | Product Description   | Classification | Code Info                     | Reason for Recall  | Recalling Firm             |
|--------------|---|----------------|-------------------------------|--|----------------------------|
| Drugs        | Rhino 69 Extreme 50000 packaged in 1 capsule per blister pack, Distributed by AMA Wholesale Inc. Chino Hills, CA, 91709-2618, UPC Code: 718122071128                    | Class I        | All Lots                      | Marketed Without An Approved NDA/ANDA: FDA analysis found the product to contain undeclared tadalafil. The presence of tadalafil makes Rhino Extreme 50000 an unapproved drug for which safety and efficacy have not been established and, therefore, subject to recall.                       | AMA Wholesale              |
| Drugs        | POSEIDON Xtreme PLATINUM 4500,1000mg, packaged in single packs sold in 24-count boxes, Distributed by: Poseidon Distribution Atlanta, GA, UPC 638632428857              | Class I        | Lot #: 201117BL, Exp. 01/2020 | Marketed Without An Approved NDA/ANDA: FDA analysis found products to contain undeclared sildenafil and tadalafil. The presence of sildenafil and tadalafil makes these products an unapproved drug for which safety and efficacy have not been established and, therefore, subject to recall. | Shoreside Enterprises Inc. |
| Drugs        | 7K capsules packaged in single packs sold in 24-count boxes, Distributed by SX Power Co. San Diego, CA 92108, UPC 601577513148  | Class I        | Lot #: RO, Exp. 12/31/2021    | Marketed Without An Approved NDA/ANDA: FDA analysis found products to contain undeclared sildenafil and tadalafil. The presence of sildenafil and tadalafil makes these products an unapproved drug for which safety and efficacy have not been established and, therefore, subject to recall. | Shoreside Enterprises Inc. |
| Drugs        | Allergan Taytulla Softgel Capsules, 1 mg/20 mcg, 6x28 blister card Physicians' Sample - Not for Sale Distributed by: Allergan USA INC Irvine, CA 92612 NDC 0023-5862-28 | Class I        | Lot# 5620706, Exp. 05/19      | Contraceptive Tablets Out of Sequence.   | Allergan, PLC.             |

| Product Type | Product Description  | Classification | Code Info   | Reason for Recall              | Recalling Firm                                    |
|--------------|--|----------------|---|--------------------------------|---|
|              | (Blister Card) NDC 0023-5862-29<br>(Blister Carton) NDC 0023-5862-31 (Outer carton) UPC 300235862290                               |                |   |                                |   |
| Drugs        | 0.9% Sodium Chloride Injection, USP, 1000 mL, Rx Only, Fresenius Medical Care North America, Waltham, MA 02451, NDC 49230-0300-10. | Class II       | Lot # 17LU05005; Exp. 09/18 Part Number 060-10109   | Lack of Assurance of Sterility | Fresenius Medical Care Renal Therapies Group, LLC |
| Drugs        | Loxapine Capsules, USP 25 mg, Rx Only, 100-count bottles, NDC 0378-7025-01   | Class II       | NDC # 0378-7025-01<br>Lot Numbers: 3083756, Exp. 3/31/19<br>3083757, Exp. 3/31/19<br>3083758, Exp. 3/31/19<br>3083759, Exp. 3/31/19<br>3083760, Exp. 3/31/19<br>3083761, Exp. 3/31/19 | CGMP Deviations                | Mylan Pharmaceuticals Inc.                        |
| Drugs        | Loxapine Capsules, USP 50 mg, Rx Only, 100-count bottles, NDC 0378-7050-01   | Class II       | NDC 0378-7050-01<br>Lot Numbers: 3079386, Exp.  | CGMP Deviations                | Mylan Pharmaceuticals Inc.                        |

| Product Type | Product Description   | Classification | Code Info  | Reason for Recall  | Recalling Firm |
|--------------|---|----------------|--|--|----------------|
|              |   |                | 10/31/18<br>3079387,<br>Exp.<br>10/31/18<br>3079388,<br>Exp.<br>10/31/18<br>3083762,<br>Exp.<br>3/31/19<br>3083763,<br>Exp.<br>3/31/19<br>3083764,<br>Exp.<br>3/31/19<br>3083765,<br>Exp.<br>3/31/19<br>3083766,<br>Exp.<br>3/31/19<br>3083767,<br>Exp.<br>3/31/19 |  |                |
| Drugs        | screamin' hot<br>(capsaicin) Pain<br>Relieving Gel,<br>0.03%, packaged<br>in a) 2 OZ (57g)<br>tubes, UPC 7<br>50263 80072 4; b)<br>5 oz. (141g) tubes,<br>UPC 7 50263<br>80007 6; and c) 16<br>oz. (454g) bottles,<br>UPC 7 50263<br>80076 2; MFD<br>FOR: Toast<br>Products, 400<br>Sproul Street,<br>Pittsburgh, PA<br>15136; NDC<br>52099-8005. | Class II       | Lot #:<br>116002, Exp<br>01/19;<br>217003, Exp<br>02/20;<br>1217017,<br>Exp 12/20  | CGMP Deviations: Products<br>manufactured with an<br>ingredient that exceed the<br>benzene levels allowed in drug<br>products. | Ideaz Llc      |

| Product Type | Product Description  | Classification | Code Info                                     | Reason for Recall   | Recalling Firm                                      |
|--------------|--|----------------|---|---|---|
| Drugs        | screamin' menthol (menthol) Pain Relieving Gel, 4%, packaged in a) 2 OZ (57g) tubes, UPC 7 50263 80062 5; b) 5 oz. (141g) tubes, UPC 7 50263 80006 9; and c) 16 oz. (454g) bottles, UPC 7 50263 80066 3; MFD FOR: Toast Products, 400 Sproul Street, Pittsburgh, PA 15136; NDC 52099-8010. | Class II       | Lot #: 1015019, Exp 10/18; 1116011, Exp 11/19 | CGMP Deviations: Products manufactured with an ingredient that exceed the benzene levels allowed in drug products.  | Ideaz Llc   |
| Drugs        | Diclofenac Sodium and Misoprostol Delayed Release Tablets 75 mg/0.2 mg, 60-count bottle, Rx Only, Manufactured by: Cipla Ltd., India; For: EAGLE PHARMACEUTICALS, INC., Woodcliff Lake, NJ 07677 USA, NDC 42367-111-06.  | Class II       | Lot: GH70154, Exp 12/18                       | Labeling: Label Mix-Up: bottle labeled as Diclofenac Sodium and Misoprostol 75 mg/0.2 mg contained Diclofenac Sodium and Misoprostol 50 mg/0.2 mg tablets.    | Exela Pharma Sciences LLC                           |
| Drugs        | Loxapine Capsules, USP 25 mg, packaged in 100 Unit Dose Capsules, Rx only, Manufactured by Mylan Pharmaceuticals Inc. Morgantown, WV 26505 U.S.A. NDC 51079-902-20   | Class II       | Lot #: 3090454, Exp. 03/2019                  | GMP Deviations: a recent FDA inspection of the manufacturing site revealed multiple cGMP violations that would place Loxapine at risk for cross contamination | Mylan Institutional, Inc. (d.b.a. UDL Laboratories) |

| Product Type | Product Description   | Classification | Code Info  | Reason for Recall   | Recalling Firm                                      |
|--------------|---|----------------|--|---|---|
| Drugs        | Loxapine Capsules, USP 50 mg, packaged in 100 Unit Dose capsules, Rx only, Manufactured by Mylan Pharmaceuticals Inc. Morgantown, WV 26505 U.S.A. NDC 51079-903-20. | Class II       | Lot #: 3092310, Exp. 03/2019   | GMP Deviations: a recent FDA inspection of the manufacturing site revealed multiple cGMP violations that would place Loxapine at risk for cross contamination | Mylan Institutional, Inc. (d.b.a. UDL Laboratories) |
| Drugs        | PrednisolONE Sodium Phosphate Orally Disintegrating Tablets 10 mg, Rx Only, 48-count bottle, NDC 00378-4710-22  | Class II       | Lot #: 3081542, Exp. 08/18<br>3081543, Exp. 08/18<br>3081544, Exp. 08/18<br>3082235, Exp. 08/18<br>3085903, Exp. 12/18<br>3088974, Exp. 06/19<br>3090445, Exp. 06/19 | CGMP Deviations   | Mylan Pharmaceuticals Inc.                          |
| Drugs        | PrednisolONE Sodium Phosphate Orally Disintegrating Tablets 15 mg, Rx Only, 48-count bottle, NDC 00378-4715-22  | Class II       | Lot #: 3082509; Exp. 08/18<br>3085901; Exp. 12/18  | CGMP Deviations   | Mylan Pharmaceuticals Inc.                          |
| Drugs        | PrednisolONE Sodium Phosphate Orally Disintegrating Tablets, 30 mg, Rx Only, 48-count bottle, NDC 00378-4730-22   | Class II       | Lot #: 3082921; Exp. 12/18<br>3088975; Exp. 06/19  | CGMP Deviations   | Mylan Pharmaceuticals Inc.                          |

| Product Type | Product Description  | Classification | Code Info                                      | Reason for Recall   | Recalling Firm             |
|--------------|--|----------------|--|---|----------------------------|
| Drugs        | My Way (Levonorgestrel) Tablets TWO PACK, 1.5 mg each, packaged as 2 Treatments (Two 1.5mg Levonorgestrel Tablets) per carton, GAVIS Pharmaceuticals, A Lupin Group Company; Mfg. for Lupin Pharmaceuticals, Inc., Baltimore, MD 21202, UPC 3 43386-622-31 3.                              | Class II       | Lot #: M16317A1, M16317A4, M16317A5, Exp 11/18 | Marketed Without an Approved NDA/ANDA: 2-pack configuration did not receive appropriate regulatory approval prior to release. | Lupin Pharmaceuticals Inc. |
| Drugs        | My Way (levonorgestrel) Tablets TWO PACK, 1.5 mg each, packaged as 2 Treatments (Two 1.5mg Levonorgestrel Tablets) per carton, Manufactured for: Lupin Pharmaceuticals, Inc., Baltimore, MD 21202; Manufactured by: Lupin Limited, Pithampur (M.P.) - 454 775, INDIA, UPC 3 68180 85212 4. | Class II       | Lot #: L700329, Exp 08/19; L700670, Exp 11/19  | Marketed Without an Approved NDA/ANDA: 2-pack configuration did not receive appropriate regulatory approval prior to release. | Lupin Pharmaceuticals Inc. |
| Drugs        | Fluticasone propionate Nasal Spray, USP, 50 mcg, packaged in 50 mcg per spray 120 Metered  | Class II       | Lot: NJ4501 Exp. 07/2020                       | Presence of foreign substance: glass particles  | Apotex Inc.                |

| Product Type | Product Description  | Classification | Code Info                                     | Reason for Recall  | Recalling Firm         |
|--------------|--|----------------|---|--|------------------------|
|              | Sprays bottles, 16 g net fill weight, Rx Only, Manufactured by: Apotex Inc. Toronto, Ontario Canada M9L 1T9 Manufactured for: Apotex Corp. Weston, FL 33326, NDC 60505-0829-1  |                |   |  |                        |
| Drugs        | Preferred Plus Pharmacy Antacid Extra Strength (Aluminum Hydroxide 400mg, Magnesium Hydroxide 400mg, Simethicone 40 mg), packaged in 12 FL. OZ. (355 mL), Manufactured By: RIJ Pharmaceutical Corp.40 Commercial Avenue, Middletown, NY 10941, Distributed by: Kinray Inc. Whitestone, NY 11357 NDC 53807-158-12, UPC 353807158123 | Class II       | Lot #: 707007, Exp. 07/19                     | CGMP Deviations: Products are being recalled due to an out of specification total aerobic microbial count in a water sample. | RIJ Pharmaceutical LLC |
| Drugs        | Preferred Plus Pharmacy Antacid (Aluminum Hydroxide 200mg, Magnesium Hydroxide 200mg Simethicone 20mg, packaged in   | Class II       | Lot #: 707006, Exp. 07/19; 708001, Exp. 08/19 | CGMP Deviations: Products are being recalled due to an out of specification total aerobic microbial count in a water sample. | RIJ Pharmaceutical LLC |



| Product Type | Product Description  | Classification | Code Info                   | Reason for Recall  | Recalling Firm         |
|--------------|--|----------------|-----------------------------|--|------------------------|
|              | 12 FL. OZ. (355 mL) bottles,<br>Manufactured By:<br>RIJ<br>PHARMACEUTICAL CORPORATION<br>40 Commercial Avenue<br>Middletown, NY<br>10941, Distributed by: Kinray Inc.<br>Whitestone, NY<br>11357, NDC<br>53807-12612, UPC<br>53807126122 |                |                             |  |                        |
| Drugs        | RPC Senna Syrup (Sennosides 8.8mg), packaged in 8 fl oz (237 mL) bottles, RIJ Pharmaceuticals Corporation 40 Commercial Avenue, Middletown, NJ 10941, NDC 5380755608, UPC 353807556080   | Class II       | Lot #: 47070081, Exp 09/18  | CGMP Deviations: Products are being recalled due to an out of specification total aerobic microbial count in a water sample. | RIJ Pharmaceutical LLC |
| Drugs        | RPC Children's Non-Aspirin (Acetaminophen 160 mg) Elixir, packaged in 4 FL. OZ. (118 mL), RIJ PHARMACEUTICAL CORPORATION, 40 COMMERCIAL AVENUE, MIDDLETOWN, NY 10941, NDC 53807-129-04, UPC 353807129048                                 | Class II       | Lot #: 47080091, Exp. 08/19 | CGMP Deviations: Products are being recalled due to an out of specification total aerobic microbial count in a water sample. | RIJ Pharmaceutical LLC |

| Product Type | Product Description   | Classification | Code Info                                       | Reason for Recall  | Recalling Firm         |
|--------------|---|----------------|---|--|------------------------|
| Drugs        | Gericare Liquid Pain Relief Acetaminophen Cherry Flavor 160mg/5mL, packaged in 16 FL OZ (473 mL), Dist. By Gericare Pharmaceuticals 1650 63rd Street Brooklyn, NY 11204, NDC 5789618016, UPC 357896180164 | Class II       | Lot #: 47080081, 47080093, Exp. 08/19           | CGMP Deviations: Products are being recalled due to an out of specification total aerobic microbial count in a water sample. | RIJ Pharmaceutical LLC |
| Drugs        | RPC APAP Elixir (Acetaminophen 160mg), Packaged in 16 FL. OZ. (473 mL) bottles, RIJ PHARMACEUTICAL CORPORATION, 40 COMMERCIAL AVENUE, MIDDLETOWN, NY, NDC 53807-129-16, UPC 353807129161                  | Class II       | Lot #: 47080092, Exp 08/19                      | CGMP Deviations: Products are being recalled due to an out of specification total aerobic microbial count in a water sample. | RIJ Pharmaceutical LLC |
| Drugs        | GeriCare Senna Syrup (Sennosides 8.8 mg), 8 fl oz (237 mL) bottles, Dist, by Gericare Pharmaceuticals 1650 63rd Street Brooklyn, NY 11204, NDC 57696-452-08, UPC 357896452087                             | Class II       | Lot #: 47070082, 47070043, 47070011, Exp. 09/18 | CGMP Deviations: Products are being recalled due to an out of specification total aerobic microbial count in a water sample. | RIJ Pharmaceutical LLC |
| Drugs        | Ritussin DM Dextromethorphan Hydrobromide (Dextromethorphan HBr, USP 10 mg, Guaifenesin,  | Class II       | Lot #: 47070021, Exp. 07/19                     | CGMP Deviations: Products are being recalled due to an out of specification total aerobic microbial count in a water sample. | RIJ Pharmaceutical LLC |

| Product Type | Product Description   | Classification | Code Info  | Reason for Recall  | Recalling Firm         |
|--------------|---|----------------|--|--|------------------------|
|              | USP 100mg), packaged in 4 FL.OZ. (118 mL), RIJ PHARMACEUTICAL CORPORATION 40 COMMERCIAL AVENUE, MIDDLETOWN, NY 10941, NDC 5380740904, UPC 35380740941   |                |  |  |                        |
| Drugs        | Geritrex Senna Syrup (sennosides 8.8mg), packaged in 8 FL OZ. (236 mL) bottle, Distributed by Geritrex, LLC 144 Kingsbridge Rd East Mt Vernon, NY 10550, 1-800-736-3437, NDC 54162-007-08, UPC 354162007088 | Class II       | Lot #: 47060011, 47070031, 47070041, Exp. 09/18; 47080031, Exp.10/18 | CGMP Deviations: Products are being recalled due to an out of specification total aerobic microbial count in a water sample. | RIJ Pharmaceutical LLC |
| Drugs        | SDA Senna Syrup (Sennosides 8.8mg), packaged in 8 FL. OZ. (236 mL) bottles, Distributed by SDA Laboratories 280 Railroad Avenue, Greenwich CT 06830, NDC 66424-562-08, UPC 366424562082                     | Class II       | Lot #: 47070042, Exp. 09/18  | CGMP Deviations: Products are being recalled due to an out of specification total aerobic microbial count in a water sample. | RIJ Pharmaceutical LLC |
| Drugs        | Gericare Diocto Liquid (Docusate Sodium 50mg), 50 mg/5 mL, packaged in 16 FL  | Class II       | Lot #: 47080041, 47080051, Exp. 08/19                                | CGMP Deviations: Products are being recalled due to an out of specification total aerobic microbial count in a water sample. | RIJ Pharmaceutical LLC |

| Product Type | Product Description  | Classification | Code Info                  | Reason for Recall  | Recalling Firm                               |
|--------------|--|----------------|----------------------------|--|--|
|              | OZ (473 mL) bottles, Dist by: Gericare Pharmaceuticals Corp. 1650 63rd Street, Brooklyn, NY 11204, NDC 57896-403-16, UPC 357896-403164,  |                |                            |  |  |
| Drugs        | Gericare Iron Supplement Elixir Ferrous Sulfate 220 mg, packaged in 16 fl oz. (473 mL) bottles, Dist by: Gericare Pharmaceuticals Corp. 1650 63rd Street Brooklyn, NY 11204, NDC 57896-709-16, UPC 57896709167 | Class II       | Lot #: 4780111, Exp. 08/19 | CGMP Deviations: Products are being recalled due to an out of specification total aerobic microbial count in a water sample.   | RIJ Pharmaceutical LLC                       |
| Drugs        | Teething Drops, Homeopathic Drops for Temporary Relief of Pain Caused by Teething, 1 Fl Ounce glass amber bottle with glass dropper, MBI Nutraceuticals, Lindon, UT 84042. Bar Code: 3 58301 04011 0           | Class II       | Lot: 15041402, No EXP date | Lack of Processing Controls: Firm is voluntarily recalling all lots of homeopathic Teething Drops, Nausea Drops, Intestinal Colic Drops, Stomach Calm, Expectorant Cough Syrup, Silver-Zinc Throat Spray, and Argentum Elixir, within expiry, due to lack of adequate controls during manufacturing. | MBi Distributing Inc. dba MBI Nutraceuticals |
| Drugs        | Nausea Drops, Homeopathic Drops for Temporary Relief of Motion Sickness, Morning Sickness, and General Nausea, 1   | Class II       | Lot: 17011201, No EXP Date | Lack of Processing Controls: Firm is voluntarily recalling all lots of homeopathic Teething Drops, Nausea Drops, Intestinal Colic Drops, Stomach Calm, Expectorant Cough Syrup, Silver-Zinc Throat Spray, and Argentum Elixir, within expiry,  | MBi Distributing Inc. dba MBI Nutraceuticals |

| Product Type | Product Description  | Classification | Code Info   | Reason for Recall  | Recalling Firm                               |
|--------------|--|----------------|---|--|--|
|              | Fl. Ounce amber glass bottle with glass dropper. MBI Nutraceuticals Lindon, UT 84042. Bar Code: 1 58301 04711 4  |                |   | due to lack of adequate controls during manufacturing.   |  |
| Drugs        | Intestinal Colic Drops, Homeopathic Drops for Temporary Relief of Flatulent Colic, 1 ounce amber glass bottle with glass dropper, liquid, Meteorism, and Porphyriuria. MBI Nutraceuticals Lindon, UT 84042 | Class II       | Lot: 8040802, EXP 04/2021.  | Lack of Processing Controls: Firm is voluntarily recalling all lots of homeopathic Teething Drops, Nausea Drops, Intestinal Colic Drops, Stomach Calm, Expectorant Cough Syrup, Silver-Zinc Throat Spray, and Argentum Elixir, within expiry, due to lack of adequate controls during manufacturing. | MBi Distributing Inc. dba MBI Nutraceuticals |
| Drugs        | Stomach Calm, Calms Upset Stomach and Aids in Treatment of Simple Diarrhea, 8 fl. oz., liquid 8 ounce amber PET bottle with Black CRC Cap, MBI Nutraceuticals Lindon, UT 84042. Bar Code: 3 58301 38414 2  | Class II       | Lot: 14093001, EXP 09/2020  | Lack of Processing Controls: Firm is voluntarily recalling all lots of homeopathic Teething Drops, Nausea Drops, Intestinal Colic Drops, Stomach Calm, Expectorant Cough Syrup, Silver-Zinc Throat Spray, and Argentum Elixir, within expiry, due to lack of adequate controls during manufacturing. | MBi Distributing Inc. dba MBI Nutraceuticals |
| Drugs        | Expectorant Cough Syrup, Homeopathic Syrup for Temporary Relief of Cough & Bronchitis. 8 Fl Ounces amber PET bottle with black cap. MBI Nutraceuticals   | Class II       | Lot numbers: 16081901, EXP: 08/2018; 17031604, EXP: 03/2019; 17110901, EXP: 11/2019 | Lack of Processing Controls: Firm is voluntarily recalling all lots of homeopathic Teething Drops, Nausea Drops, Intestinal Colic Drops, Stomach Calm, Expectorant Cough Syrup, Silver-Zinc Throat Spray, and Argentum Elixir, within expiry, due to lack of adequate controls during manufacturing. | MBi Distributing Inc. dba MBI Nutraceuticals |

| Product Type | Product Description   | Classification | Code Info  | Reason for Recall   | Recalling Firm  |
|--------------|---|----------------|--|---|---|
|              | 211 N 1800 W,<br>Lindon, UT 84042.<br>Bar Code: 3 58301<br>08214 1  |                |  |   |   |
| Drugs        | Argentum Elixir<br>Colloidal Silver, 50<br>PPM Homeopathic<br>Infection Fighter,<br>8 fl oz. amber PET<br>bottle with white<br>sprayer. MBI<br>nutraceuticals<br>Lindon UT, 84042.<br>Bar COde: 3 58301<br>18114 1  | Class II       | Lot numbers<br>15060201,<br>EXP:<br>06/2019,<br>16081704,<br>EXP:<br>08/2020 | Lack of Processing Controls:<br>Firm is voluntarily recalling all<br>lots of homeopathic Teething<br>Drops, Nausea Drops, Intestinal<br>Colic Drops, Stomach Calm,<br>Expectorant Cough Syrup,<br>Silver-Zinc Throat Spray, and<br>Argentum Elixir, within expiry,<br>due to lack of adequate<br>controls during manufacturing. | MBi<br>Distributi<br>ng Inc.<br>dba MBI<br>Nutraceu<br>ticals |
| Drugs        | Silver-Zinc Throat<br>Spray,<br>HOMEOPATHIC<br>IMMUNE<br>DEFENSE, 50PPM,<br>4oz/50 ppm/<br>120ml, amber PET<br>bottle with white<br>sprayer. MBI<br>Nutraceuticals<br>Lindon, Utah<br>84042 USA. Bar<br>Code: 3 58301<br>18118 9  | Class II       | Lot:<br>15050801,<br>EXP<br>05/2018  | Lack of Processing Controls:<br>Firm is voluntarily recalling all<br>lots of homeopathic Teething<br>Drops, Nausea Drops, Intestinal<br>Colic Drops, Stomach Calm,<br>Expectorant Cough Syrup,<br>Silver-Zinc Throat Spray, and<br>Argentum Elixir, within expiry,<br>due to lack of adequate<br>controls during manufacturing. | MBi<br>Distributi<br>ng Inc.<br>dba MBI<br>Nutraceu<br>ticals |
| Drugs        | X-Jow (menthol<br>USP) Pain Gel,<br>1.25%, packaged<br>in a) 4 oz. (113g)<br>bottles (UPC<br>850547 00502 6)<br>and b) 8 oz. (226g)<br>bottles (UPC 8<br>50547 00503 3,<br>Distributed by<br>Herb-X Solutions,<br>Inc., 3838 West<br>Burbank Blvd.,<br>Burbank CA<br>91505. | Class II       | All lots   | CGMP Deviations: products<br>may be contaminated with<br>bacteria.  | Shadow<br>Holdings<br>DBA<br>Bocchi<br>Labs                   |
| Drugs        | Acne Shave Post-  | Class II       | All lots   | CGMP Deviations: products   | Shadow  |

| Product Type | Product Description   | Classification | Code Info       | Reason for Recall  | Recalling Firm                  |
|--------------|---|----------------|-----------------|--|---------------------------------|
|              | Shave Moisturizer (salicylic acid), 0.5%, 3.3 FL OZ (98 mL) tube, Distributed by: United Exchange Corp., 17211 Valley View Blvd., Cerritos, CA 90703 USA, UPC 7 80707 73112 3.  |                |                 | may be contaminated with bacteria.                           | Holdings DBA Bocchi Labs        |
| Drugs        | Acne Shave (salicylic acid) Shave Cream Acne Shield, 0.5%, 5.1 FL OZ (150 mL) tube, Distributed by: United Exchange Corp., 17311 Valley View Blvd, Cerritos, CA 90703 USA, UPC 7 80707 73111 6.   | Class II       | All lots        | CGMP Deviations: products may be contaminated with bacteria. | Shadow Holdings DBA Bocchi Labs |
| Drugs        | Acne Shave 3 Step Shaving System, contains one tube Acne Shave (salicylic acid) Shave Cream Acne Shield, one tube Acne Shave Post-Shave Moisturizer (salicylic acid), 0.5% tube, and one Power Shaver per box, Distributed by: United Exchange Corp., 17311 Valley View Blvd, Cerritos CA 90703 USA, UPC 7 80707 73114 7. | Class II       | All lots        | CGMP Deviations: products may be contaminated with bacteria. | Shadow Holdings DBA Bocchi Labs |
| Drugs        | READYFLUSH PROTECT with   | Class II       | Lot # 18BE0005, | Microbial Contamination of a Non-Sterile Product.            | Medline Industrie               |



| Product Type | Product Description  | Classification | Code Info   | Reason for Recall  | Recalling Firm              |
|--------------|--|----------------|---|--|-----------------------------|
|              | Dimethicone (3.2%), Flushable Personal Cleaning Cloths, 24-count flexible pack. Manufactured by Medline Industries, Inc. Mundelein, IL 60060 USA. NDC 53329-066-58.  |                | 18BE0006, Exp. 02/2020  |  | s Inc (Northpoint Services) |
| Drugs        | Option Systems Antibacterial Foaming Hand Wash with .3% PCMX, 1000 mL pouches, Inopak, LTD, Ringwood, NJ   | Class II       | 7302 01 039, 7302 03 039, 7302 01 040 and 7302 01 043   | Microbial contamination of NonSterile Product; FDA analysis returned out of specification results for total aerobic microbial counts | Inopak Ltd                  |
| Drugs        | HYDROmorphone HCl 0.5 mg per mL in 0.9% Sodium Chloride, 1 mL Total Volume in 3 mL syringe, Rx, PharMEDium Services, LLC, Dayton, NJ   | Class II       | Lot numbers: 180820005 D, exp 6/21/2018; 180990007 D, exp 7/8/2018; and 181000020 D, exp 7/9/2018 | Superpotent and Subpotent  | PharMEDium Services, LLC    |
| Drugs        | Monsel's Solution (Ferric Sub sulfate), 20%, packaged as 12 single application vials and 12 applicators, 8 mL per box, Manufactured For: MedGyn Products, Inc., 100 W. Industrial Rd., Addison, IL 60101 USA; Manufactured By: | Class II       | All lots within expiry  | CGMP Deviations: Products not manufactured under current good manufacturing practices.   | BioDiagnostic International |



| Product Type | Product Description  | Classification | Code Info   | Reason for Recall               | Recalling Firm            |
|--------------|--|----------------|---|---------------------------------|---------------------------|
|              | BioDiagnostics Intl, 555 West Lambert Road Unit-C, Brea, CA 92821, NDC 42721-112-08.   |                |   |                                 |                           |
| Drugs        | Lidocaine Patch 5% (700 mg), (NDC 0591-3525-11), 30 envelopes containing 1 patch each/ 30 Patches/ Carton (NDC 0591-3525-30)                         | Class III      | Carton Lot Number:1147020B Patch (Envelope) Lot Number: 1147020               | Failed Stability Specifications | Teva Pharmaceuticals USA  |
| Drugs        | T Shampoo For Hair and Body, Solution Coal Tar 3% (0.6% coal tar), 300 ml/10.1 fl. oz. bottles, Dermatologic Cosmetic Laboratories, East Haven, CT   | Class III      | Lot # MT390-8, expiration date 12/01/2020 GU925-4, expiration date 07/05/2020 | Subpotent                       | Milbar Laboratories, Inc. |
| Drugs        | Zoma Shampoo, Zinc Pyrithione 1.92%, 300 ml/10.01 fl. oz. bottles, Dermatologic Cosmetic Laboratories, East Haven, CT                                | Class III      | Lot # HT659-6, expiration date 08/11/2019 LT168-7, expiration date 11/10/2019 | Subpotent                       | Milbar Laboratories, Inc. |
| Drugs        | Hydrocodone Bitartrate and Acetaminophen Tablets, USP, 5 mg/325 mg, 1000-count bottle Rx Only, Manufactured by: Novel Laboratories, Inc. Somerset NJ | Class III      | Lot # S800257; Exp. 01/20   | Labeling: Missing Label         | LUPIN SOMERSET            |

| Product Type | Product Description  | Classification | Code Info   | Reason for Recall   | Recalling Firm                                  |
|--------------|--|----------------|---|---|---|
|              | 08873<br>Manufactured for:<br>Lupin<br>Pharmaceuticals,<br>Inc. Baltimore,<br>MD 212020 NDC<br>43386-356-10<br>UPC<br>343386356102   |                |   |   |   |
| Drugs        | Valsartan Tablets<br>USP, 320 mg, 90<br>tablet, Rx Only,<br>Manufactured by:<br>Jubilant Generics<br>Ltd. Roorkee -<br>247661, India,<br>Marketed by:<br>Jubilant Cadista<br>Pharmaceuticals,<br>Inc., Salisbury, MD<br>21801, NDC<br>59746-363-90 | Class III      | Lot #:<br>VR417065A,<br>VR417066A,<br>Exp 10/2019 | Incorrect/Undeclared<br>excipient: Product batches<br>were released into commercial<br>distribution with a larger size<br>grade of excipient<br>(Crospovidone). | Jubilant<br>Cadista<br>Pharmaceuticals,<br>Inc. |
| Drugs        | Nystatin Oral<br>Suspension, USP,<br>500,000 units/5<br>mL, For<br>Institutional Use<br>Only, packaged in<br>5 mL cups, Rx<br>Only,<br>Pharmaceutical<br>Associates, Inc.<br>Greenville, SC<br>29605, NDC 0121-<br>4810-05                         | Class III      | Lot: B5B8<br>Exp.<br>07/2019                      | Resuspension problems: Out of<br>specification for appearance<br>and resuspendability.  | Pharmaceutical<br>Associates Inc                |
| Drugs        | Maxzide-25<br>(Triamterene and<br>hydrochlorothiazide)<br>tablets, USP,<br>37.5 mg/ 25 mg,<br>100-count bottle,<br>Rx only, Mylan<br>Pharmaceuticals<br>Inc., Morgantown,<br>WV 26505, NDC   | Class III      | Lot #:<br>3087136,<br>Exp 5/20                    | Superpotent Drug: Composite<br>assay results obtained during<br>routine stability testing were<br>slightly above specification.                                 | Mylan<br>Pharmaceuticals<br>Inc.                |

| Product Type | Product Description   | Classification     | Code Info  | Reason for Recall  | Recalling Firm             |
|--------------|---|--------------------|--|--|----------------------------|
|              | 0378-0464-01  |                    |  |  |                            |
| Drugs        | Naloxone Hydrochloride Injection, USP, 0.4 mg/mL, 1 mL in 2.5 mL Carpuject Single-use cartridge syringe, Single unit (NDC 0409-1782-03) and 10 count box (NDC 0409-1782-69), Rx Only, Hospira Inc., Lake Forest, IL | Not Yet Classified | 72680LL, Exp. 1DEC2018 (NDC 0409-1782-03); 76510LL, Exp. 1APR2019 (NDC 0409-1782-69) | Presence of Particulate Matter; Potential for particulate matter on the syringe plunger.   | HOSPIRA INC, LAKE FOREST   |
| Product Type | Product Description   | Classification     | Code Info  | Reason for Recall  | Recalling Firm             |
| Drugs        | Rhino 69 Extreme 50000 packaged in 1 capsule per blister pack, Distributed by AMA Wholesale Inc. Chino Hills, CA, 91709-2618, UPC Code: 718122071128  | Class I            | All Lots   | Marketed Without An Approved NDA/ANDA: FDA analysis found the product to contain undeclared tadalafil. The presence of tadalafil makes Rhino Extreme 50000 an unapproved drug for which safety and efficacy have not been established and, therefore, subject to recall.                       | AMA Wholesale              |
| Drugs        | POSEIDON Xtreme PLATINUM 4500,1000mg, packaged in single packs sold in 24-count boxes, Distributed by: Poseidon Distribution Atlanta, GA, UPC 638632428857  | Class I            | Lot #: 201117BL, Exp. 01/2020  | Marketed Without An Approved NDA/ANDA: FDA analysis found products to contain undeclared sildenafil and tadalafil. The presence of sildenafil and tadalafil makes these products an unapproved drug for which safety and efficacy have not been established and, therefore, subject to recall. | Shoreside Enterprises Inc. |
| Drugs        | 7K capsules packaged in single packs sold in 24-count boxes, Distributed by SX Power Co. San Diego, CA 92108,   | Class I            | Lot #: RO, Exp. 12/31/2021   | Marketed Without An Approved NDA/ANDA: FDA analysis found products to contain undeclared sildenafil and tadalafil. The presence of sildenafil and tadalafil makes these products an unapproved   | Shoreside Enterprises Inc. |

| Product Type | Product Description  | Classification | Code Info  | Reason for Recall   | Recalling Firm                                    |
|--------------|--|----------------|--|---|---|
|              | UPC<br>601577513148  |                |  | drug for which safety and efficacy have not been established and, therefore, subject to recall. |   |
| Drugs        | Allergan Taytulla Softgel Capsules, 1 mg/20 mcg, 6x28 blister card<br>Physicians' Sample - Not for Sale Distributed by: Allergan USA INC Irvine, CA 92612 NDC 0023-5862-28 (Blister Card) NDC 0023-5862-29 (Blister Carton) NDC 0023-5862-31 (Outer carton) UPC 300235862290 | Class I        | Lot#<br>5620706,<br>Exp. 05/19   | Contraceptive Tablets Out of Sequence.  | Allergan, PLC.                                    |
| Drugs        | 0.9% Sodium Chloride Injection, USP, 1000 mL, Rx Only, Fresenius Medical Care North America, Waltham, MA 02451, NDC 49230-0300-10.   | Class II       | Lot #<br>17LU05005;<br>Exp. 09/18<br>Part<br>Number<br>060-10109   | Lack of Assurance of Sterility  | Fresenius Medical Care Renal Therapies Group, LLC |
| Drugs        | Loxapine Capsules, USP 25 mg, Rx Only, 100-count bottles, NDC 0378-7025-01   | Class II       | NDC # 0378-7025-01<br>Lot<br>Numbers:<br>3083756,<br>Exp.<br>3/31/19<br>3083757,<br>Exp.<br>3/31/19<br>3083758,<br>Exp.<br>3/31/19 | CGMP Deviations   | Mylan Pharmaceuticals Inc.                        |

| Product Type | Product Description  | Classification | Code Info  | Reason for Recall  | Recalling Firm             |
|--------------|--|----------------|--|--|----------------------------|
|              |  |                | 3083759,<br>Exp.<br>3/31/19<br>3083760,<br>Exp.<br>3/31/19<br>3083761,<br>Exp.<br>3/31/19  |  |                            |
| Drugs        | Loxapine Capsules, USP 50 mg, Rx Only, 100-count bottles, NDC 0378-7050-01     | Class II       | NDC 0378-7050-01<br>Lot Numbers:<br>3079386,<br>Exp.<br>10/31/18<br>3079387,<br>Exp.<br>10/31/18<br>3079388,<br>Exp.<br>10/31/18<br>3083762,<br>Exp.<br>3/31/19<br>3083763,<br>Exp.<br>3/31/19<br>3083764,<br>Exp.<br>3/31/19<br>3083765,<br>Exp.<br>3/31/19<br>3083766,<br>Exp.<br>3/31/19<br>3083767,<br>Exp.<br>3/31/19 | CGMP Deviations  | Mylan Pharmaceuticals Inc. |
| Drugs        | screamin' hot (capsaicin) Pain Relieving Gel, 0.03%, packaged in a) 2 OZ (57g) | Class II       | Lot #:<br>116002, Exp<br>01/19;<br>217003, Exp<br>02/20;   | CGMP Deviations: Products manufactured with an ingredient that exceed the benzene levels allowed in drug products. | Ideaz Llc                  |

| Product Type | Product Description  | Classification | Code Info                                     | Reason for Recall  | Recalling Firm            |
|--------------|--|----------------|---|--|---------------------------|
|              | tubes, UPC 7 50263 80072 4; b) 5 oz. (141g) tubes, UPC 7 50263 80007 6; and c) 16 oz. (454g) bottles, UPC 7 50263 80076 2; MFD FOR: Toast Products, 400 Sproul Street, Pittsburgh, PA 15136; NDC 52099-8005.   |                | 1217017, Exp 12/20                            |  |                           |
| Drugs        | screamin' menthol (menthol) Pain Relieving Gel, 4%, packaged in a) 2 OZ (57g) tubes, UPC 7 50263 80062 5; b) 5 oz. (141g) tubes, UPC 7 50263 80006 9; and c) 16 oz. (454g) bottles, UPC 7 50263 80066 3; MFD FOR: Toast Products, 400 Sproul Street, Pittsburgh, PA 15136; NDC 52099-8010. | Class II       | Lot #: 1015019, Exp 10/18; 1116011, Exp 11/19 | CGMP Deviations: Products manufactured with an ingredient that exceeded the benzene levels allowed in drug products.                                       | Ideaz Llc                 |
| Drugs        | Diclofenac Sodium and Misoprostol Delayed Release Tablets 75 mg/0.2 mg, 60-count bottle, Rx Only, Manufactured by: Cipla Ltd., India; For: EAGLE PHARMACEUTICALS, INC., Woodcliff Lake, NJ 07677   | Class II       | Lot: GH70154, Exp 12/18                       | Labeling: Label Mix-Up: bottle labeled as Diclofenac Sodium and Misoprostol 75 mg/0.2 mg contained Diclofenac Sodium and Misoprostol 50 mg/0.2 mg tablets. | Exela Pharma Sciences LLC |

| Product Type | Product Description   | Classification | Code Info  | Reason for Recall   | Recalling Firm                                      |
|--------------|---|----------------|--|---|---|
|              | USA, NDC 42367-111-06.  |                |  |   |   |
| Drugs        | Loxapine Capsules, USP 25 mg, packaged in 100 Unit Dose Capsules, Rx only, Manufactured by Mylan Pharmaceuticals Inc. Morgantown, WV 26505 U.S.A. NDC 51079-902-20  | Class II       | Lot #: 3090454, Exp. 03/2019   | GMP Deviations: a recent FDA inspection of the manufacturing site revealed multiple cGMP violations that would place Loxapine at risk for cross contamination | Mylan Institutional, Inc. (d.b.a. UDL Laboratories) |
| Drugs        | Loxapine Capsules, USP 50 mg, packaged in 100 Unit Dose capsules, Rx only, Manufactured by Mylan Pharmaceuticals Inc. Morgantown, WV 26505 U.S.A. NDC 51079-903-20. | Class II       | Lot #: 3092310, Exp. 03/2019   | GMP Deviations: a recent FDA inspection of the manufacturing site revealed multiple cGMP violations that would place Loxapine at risk for cross contamination | Mylan Institutional, Inc. (d.b.a. UDL Laboratories) |
| Drugs        | PrednisoLONE Sodium Phosphate Orally Disintegrating Tablets 10 mg, Rx Only, 48-count bottle, NDC 00378-4710-22  | Class II       | Lot #: 3081542, Exp. 08/18<br>3081543, Exp. 08/18<br>3081544, Exp. 08/18<br>3082235, Exp. 08/18<br>3085903, Exp. 12/18<br>3088974, Exp. 06/19<br>3090445, Exp. 06/19 | CGMP Deviations   | Mylan Pharmaceuticals Inc.                          |
| Drugs        | PrednisoLONE Sodium Phosphate Orally Disintegrating   | Class II       | Lot #: 3082509; Exp. 08/18<br>3085901;   | CGMP Deviations   | Mylan Pharmaceuticals Inc.                          |

| Product Type | Product Description   | Classification | Code Info   | Reason for Recall   | Recalling Firm             |
|--------------|---|----------------|---|---|----------------------------|
|              | Tablets 15 mg, Rx Only, 48-count bottle, NDC 00378-4715-22  |                | Exp. 12/18  |   |                            |
| Drugs        | PrednisoLONE Sodium Phosphate Orally Disintegrating Tablets, 30 mg, Rx Only, 48-count bottle, NDC 00378-4730-22   | Class II       | Lot #: 3082921; Exp. 12/18<br>3088975; Exp. 06/19 | CGMP Deviations   | Mylan Pharmaceuticals Inc. |
| Drugs        | My Way (Levonorgestrel) Tablets TWO PACK, 1.5 mg each, packaged as 2 Treatments (Two 1.5mg Levonorgestrel Tablets) per carton, GAVIS Pharmaceuticals, A Lupin Group Company; Mfg. for Lupin Pharmaceuticals, Inc., Baltimore, MD 21202, UPC 3 43386-622-31 3. | Class II       | Lot #: M16317A1, M16317A4, M16317A5, Exp 11/18    | Marketed Without an Approved NDA/ANDA: 2-pack configuration did not receive appropriate regulatory approval prior to release. | Lupin Pharmaceuticals Inc. |
| Drugs        | My Way (levonorgestrel) Tablets TWO PACK, 1.5 mg each, packaged as 2 Treatments (Two 1.5mg Levonorgestrel Tablets) per carton, Manufactured for: Lupin Pharmaceuticals, Inc., Baltimore, MD 21202;  | Class II       | Lot #: L700329, Exp 08/19; L700670, Exp 11/19     | Marketed Without an Approved NDA/ANDA: 2-pack configuration did not receive appropriate regulatory approval prior to release. | Lupin Pharmaceuticals Inc. |



| Product Type | Product Description   | Classification | Code Info                    | Reason for Recall  | Recalling Firm         |
|--------------|---|----------------|------------------------------|--|------------------------|
|              | Manufactured by:<br>Lupin Limited,<br>Pithampur (M.P.) -<br>454 775, INDIA,<br>UPC 3 68180<br>85212 4.  |                |                              |  |                        |
| Drugs        | Fluticasone propionate Nasal Spray, USP, 50 mcg, packaged in 50 mcg per spray 120 Metered Sprays bottles, 16 g net fill weight, Rx Only, Manufactured by: Apotex Inc. Toronto, Ontario Canada M9L 1T9 Manufactured for: Apotex Corp. Weston, FL 33326, NDC 60505-0829-1                   | Class II       | Lot: NJ4501<br>Exp. 07/2020  | Presence of foreign substance: glass particles   | Apotex Inc.            |
| Drugs        | Preferred Plus Pharmacy Antacid Extra Strength (Aluminum Hydroxide 400mg, Magnesium Hydroxide 400mg, Simethicone 40 mg), packaged in 12 FL. OZ. (355 mL), Manufactured By: RIJ Pharmaceutical Corp.40 Commercial Avenue, Middletown, NY 10941, Distributed by: Kinray Inc. Whitestone, NY | Class II       | Lot #: 707007,<br>Exp. 07/19 | CGMP Deviations: Products are being recalled due to an out of specification total aerobic microbial count in a water sample. | RIJ Pharmaceutical LLC |

| Product Type | Product Description   | Classification | Code Info                                     | Reason for Recall  | Recalling Firm         |
|--------------|---|----------------|---|--|------------------------|
|              | 11357 NDC<br>53807-158-12,<br>UPC<br>353807158123   |                |   |  |                        |
| Drugs        | Preferred Plus Pharmacy Antacid (Aluminum Hydroxide 200mg, Magnesium Hydroxide 200mg Simethicone 20mg, packaged in 12 FL. OZ. (355 mL) bottles, Manufactured By: RIJ PHARMACEUTICAL CORPORATION 40 Commercial Avenue Middletown, NY 10941, Distributed by: Kinray Inc. Whitestone, NY 11357, NDC 53807-12612, UPC 53807126122 | Class II       | Lot #: 707006, Exp. 07/19; 708001, Exp. 08/19 | CGMP Deviations: Products are being recalled due to an out of specification total aerobic microbial count in a water sample. | RIJ Pharmaceutical LLC |
| Drugs        | RPC Senna Syrup (Sennosides 8.8mg), packaged in 8 fl oz (237 mL) bottles, RIJ Pharmaceuticals Corporation 40 Commercial Avenue, Middletown, NJ 10941, NDC 5380755608, UPC 353807556080  | Class II       | Lot #: 47070081, Exp 09/18                    | CGMP Deviations: Products are being recalled due to an out of specification total aerobic microbial count in a water sample. | RIJ Pharmaceutical LLC |
| Drugs        | RPC Children's Non-Aspirin (Acetaminophen 160 mg) Elixir, packaged in 4 FL.   | Class II       | Lot #: 47080091, Exp. 08/19                   | CGMP Deviations: Products are being recalled due to an out of specification total aerobic microbial count in a water sample. | RIJ Pharmaceutical LLC |

| Product Type | Product Description   | Classification | Code Info                                       | Reason for Recall  | Recalling Firm         |
|--------------|---|----------------|---|--|------------------------|
|              | OZ. (118 mL), RIJ PHARMACEUTICAL CORPORATION, 40 COMMERCIAL AVENUE, MIDDLETOWN, NY 10941, NDC 53807-129-04, UPC 353807129048  |                |   |  |                        |
| Drugs        | Gericare Liquid Pain Relief Acetaminophen Cherry Flavor 160mg/5mL, packaged in 16 FL OZ (473 mL), Dist. By Gericare Pharmaceuticals 1650 63rd Street Brooklyn, NY 11204, NDC 5789618016, UPC 357896180164 | Class II       | Lot #: 47080081, 47080093, Exp. 08/19           | CGMP Deviations: Products are being recalled due to an out of specification total aerobic microbial count in a water sample. | RIJ Pharmaceutical LLC |
| Drugs        | RPC APAP Elixir (Acetaminophen 160mg), Packaged in 16 FL. OZ. (473 mL) bottles, RIJ PHARMACEUTICAL CORPORATION, 40 COMMERCIAL AVENUE, MIDDLETOWN, NY, NDC 53807-129-16, UPC 353807129161                  | Class II       | Lot #: 47080092, Exp 08/19                      | CGMP Deviations: Products are being recalled due to an out of specification total aerobic microbial count in a water sample. | RIJ Pharmaceutical LLC |
| Drugs        | GeriCare Senna Syrup (Sennosides 8.8 mg), 8 fl oz (237 mL) bottles, Dist. by Gericare Pharmaceuticals 1650 63rd Street Brooklyn, NY   | Class II       | Lot #: 47070082, 47070043, 47070011, Exp. 09/18 | CGMP Deviations: Products are being recalled due to an out of specification total aerobic microbial count in a water sample. | RIJ Pharmaceutical LLC |

| Product Type | Product Description   | Classification | Code Info  | Reason for Recall  | Recalling Firm               |
|--------------|---|----------------|--|--|------------------------------|
|              | 11204, NDC<br>57696-452-08,<br>UPC<br>357896452087  |                |  |  |                              |
| Drugs        | Ritussin DM<br>Dextromethorphan Hydrobromide<br>(Dextromethorphan HBr, USP 10 mg, Guaifenesin, USP 100mg), packaged in 4 FL.OZ. (118 mL), RIJ<br>PHARMACEUTICAL CORPORATION<br>40 COMMERCIAL AVENUE,<br>MIDDLETOWN, NY 10941, NDC 5380740904, UPC 35380740941 | Class II       | Lot #:<br>47070021,<br>Exp. 07/19  | CGMP Deviations: Products are being recalled due to an out of specification total aerobic microbial count in a water sample. | RIJ<br>Pharmaceutical<br>LLC |
| Drugs        | Geritrex Senna Syrup (sennosides 8.8mg), packaged in 8 FL OZ. (236 mL) bottle,<br>Distributed by Geritrex, LLC 144 Kingsbridge Rd East Mt Vernon, NY 10550, 1-800-736-3437, NDC 54162-007-08, UPC 354162007088  | Class II       | Lot #:<br>47060011,<br>47070031,<br>47070041,<br>Exp. 09/18;<br>47080031,<br>Exp.10/18 | CGMP Deviations: Products are being recalled due to an out of specification total aerobic microbial count in a water sample. | RIJ<br>Pharmaceutical<br>LLC |
| Drugs        | SDA Senna Syrup (Sennosides 8.8mg), packaged in 8 FL. OZ. (236 mL) bottles,<br>Distributed by SDA Laboratories<br>280 Railroad Avenue,  | Class II       | Lot #:<br>47070042,<br>Exp. 09/18  | CGMP Deviations: Products are being recalled due to an out of specification total aerobic microbial count in a water sample. | RIJ<br>Pharmaceutical<br>LLC |

| Product Type | Product Description  | Classification | Code Info                             | Reason for Recall  | Recalling Firm                               |
|--------------|--|----------------|---------------------------------------|--|--|
|              | Greenwich CT 06830, NDC 66424-562-08, UPC 366424562082   |                |                                       |  |  |
| Drugs        | Gericare Diocto Liquid (Docusate Sodium 50mg), 50 mg/5 mL, packaged in 16 FL OZ (473 mL) bottles, Dist by: Gericare Pharmaceuticals Corp. 1650 63rd Street, Brooklyn, NY 11204, NDC 57896-403-16, UPC 357896-403164, | Class II       | Lot #: 47080041, 47080051, Exp. 08/19 | CGMP Deviations: Products are being recalled due to an out of specification total aerobic microbial count in a water sample.   | RIJ Pharmaceutical LLC                       |
| Drugs        | Gericare Iron Supplement Elixir Ferrous Sulfate 220 mg, packaged in 16 fl oz. (473 mL) bottles, Dist by: Gericare Pharmaceuticals Corp. 1650 63rd Street Brooklyn, NY 11204, NDC 57896-709-16, UPC 57896709167       | Class II       | Lot #: 4780111, Exp. 08/19            | CGMP Deviations: Products are being recalled due to an out of specification total aerobic microbial count in a water sample.   | RIJ Pharmaceutical LLC                       |
| Drugs        | Teething Drops, Homeopathic Drops for Temporary Relief of Pain Caused by Teething, 1 Fl Ounce glass amber bottle with glass dropper, MBI Nutraceuticals, Lindon, UT 84042.   | Class II       | Lot: 15041402, No EXP date            | Lack of Processing Controls: Firm is voluntarily recalling all lots of homeopathic Teething Drops, Nausea Drops, Intestinal Colic Drops, Stomach Calm, Expectorant Cough Syrup, Silver-Zinc Throat Spray, and Argentum Elixir, within expiry, due to lack of adequate controls during manufacturing. | MBi Distributing Inc. dba MBI Nutraceuticals |

| Product Type | Product Description  | Classification | Code Info                  | Reason for Recall  | Recalling Firm                               |
|--------------|--|----------------|----------------------------|--|--|
|              | Bar Code: 3 58301 04011 0  |                |                            |  |  |
| Drugs        | Nausea Drops, Homeopathic Drops for Temporary Relief of Motion Sickness, Morning Sickness, and General Nausea, 1 Fl. Ounce amber glass bottle with glass dropper. MBI Nutraceuticals Lindon, UT 84042. Bar Code: 1 58301 04711 4 | Class II       | Lot: 17011201, No EXP Date | Lack of Processing Controls: Firm is voluntarily recalling all lots of homeopathic Teething Drops, Nausea Drops, Intestinal Colic Drops, Stomach Calm, Expectorant Cough Syrup, Silver-Zinc Throat Spray, and Argentum Elixir, within expiry, due to lack of adequate controls during manufacturing. | MBi Distributing Inc. dba MBI Nutraceuticals |
| Drugs        | Intestinal Colic Drops, Homeopathic Drops for Temporary Relief of Flatulent Colic, 1 ounce amber glass bottle with glass dropper, liquid, Meteorism, and Porphyrinuria. MBI Nutraceuticals Lindon, UT 84042                      | Class II       | Lot: 8040802, EXP 04/2021. | Lack of Processing Controls: Firm is voluntarily recalling all lots of homeopathic Teething Drops, Nausea Drops, Intestinal Colic Drops, Stomach Calm, Expectorant Cough Syrup, Silver-Zinc Throat Spray, and Argentum Elixir, within expiry, due to lack of adequate controls during manufacturing. | MBi Distributing Inc. dba MBI Nutraceuticals |
| Drugs        | Stomach Calm, Calms Upset Stomach and Aids in Treatment of Simple Diarrhea, 8 fl. oz., liquid 8 ounce amber PET bottle with Black CRC Cap, MBI Nutraceuticals Lindon, UT 84042. Bar Code: 3 58301 38414 2                        | Class II       | Lot: 14093001, EXP 09/2020 | Lack of Processing Controls: Firm is voluntarily recalling all lots of homeopathic Teething Drops, Nausea Drops, Intestinal Colic Drops, Stomach Calm, Expectorant Cough Syrup, Silver-Zinc Throat Spray, and Argentum Elixir, within expiry, due to lack of adequate controls during manufacturing. | MBi Distributing Inc. dba MBI Nutraceuticals |
| Drugs        | Expectorant  | Class II       | Lot                        | Lack of Processing Controls:   | MBi  |

| Product Type | Product Description  | Classification | Code Info   | Reason for Recall  | Recalling Firm                               |
|--------------|--|----------------|---|--|--|
|              | Cough Syrup, Homeopathic Syrup for Temporary Relief of Cough & Bronchitis. 8 Fl Ounces amber PET bottle with black cap. MBI Nutraceuticals 211 N 1800 W, Lindon, UT 84042. Bar Code: 3 58301 08214 1 |                | numbers: 16081901, EXP: 08/2018; 17031604, EXP: 03/2019; 17110901, EXP: 11/2019 | Firm is voluntarily recalling all lots of homeopathic Teething Drops, Nausea Drops, Intestinal Colic Drops, Stomach Calm, Expectorant Cough Syrup, Silver-Zinc Throat Spray, and Argentum Elixir, within expiry, due to lack of adequate controls during manufacturing.                              | Distributing Inc. dba MBI Nutraceuticals     |
| Drugs        | Argentum Elixir Colloidal Silver, 50 PPM Homeopathic Infection Fighter, 8 fl oz. amber PET bottle with white sprayer. MBI nutraceuticals Lindon UT, 84042. Bar Code: 3 58301 18114 1                 | Class II       | Lot numbers 15060201, EXP: 06/2019, 16081704, EXP: 08/2020                      | Lack of Processing Controls: Firm is voluntarily recalling all lots of homeopathic Teething Drops, Nausea Drops, Intestinal Colic Drops, Stomach Calm, Expectorant Cough Syrup, Silver-Zinc Throat Spray, and Argentum Elixir, within expiry, due to lack of adequate controls during manufacturing. | MBI Distributing Inc. dba MBI Nutraceuticals |
| Drugs        | Silver-Zinc Throat Spray, HOMEOPATHIC IMMUNE DEFENSE, 50PPM, 4oz/50 ppm/ 120ml, amber PET bottle with white sprayer. MBI Nutraceuticals Lindon, Utah 84042 USA. Bar Code: 3 58301 18118 9            | Class II       | Lot: 15050801, EXP 05/2018  | Lack of Processing Controls: Firm is voluntarily recalling all lots of homeopathic Teething Drops, Nausea Drops, Intestinal Colic Drops, Stomach Calm, Expectorant Cough Syrup, Silver-Zinc Throat Spray, and Argentum Elixir, within expiry, due to lack of adequate controls during manufacturing. | MBI Distributing Inc. dba MBI Nutraceuticals |
| Drugs        | X-Jow (menthol USP) Pain Gel, 1.25%, packaged in a) 4 oz. (113g) bottles (UPC 850547 00502 6)  | Class II       | All lots  | CGMP Deviations: products may be contaminated with bacteria.   | Shadow Holdings DBA Bocchi Labs              |



| Product Type | Product Description   | Classification | Code Info | Reason for Recall  | Recalling Firm                  |
|--------------|---|----------------|-----------|--|---------------------------------|
|              | and b) 8 oz. (226g) bottles (UPC 8 50547 00503 3, Distributed by Herb-X Solutions, Inc., 3838 West Burbank Blvd., Burbank CA 91505.   |                |           |  |                                 |
| Drugs        | Acne Shave Post-Shave Moisturizer (salicylic acid), 0.5%, 3.3 FL OZ (98 mL) tube, Distributed by: United Exchange Corp., 17211 Valley View Blvd., Cerritos, CA 90703 USA, UPC 7 80707 73112 3.        | Class II       | All lots  | CGMP Deviations: products may be contaminated with bacteria. | Shadow Holdings DBA Bocchi Labs |
| Drugs        | Acne Shave (salicylic acid) Shave Cream Acne Shield, 0.5%, 5.1 FL OZ (150 mL) tube, Distributed by: United Exchange Corp., 17311 Valley View Blvd, Cerritos, CA 90703 USA, UPC 7 80707 73111 6.       | Class II       | All lots  | CGMP Deviations: products may be contaminated with bacteria. | Shadow Holdings DBA Bocchi Labs |
| Drugs        | Acne Shave 3 Step Shaving System, contains one tube Acne Shave (salicylic acid) Shave Cream Acne Shield, one tube Acne Shave Post-Shave Moisturizer (salicylic acid), 0.5% tube, and one Power Shaver | Class II       | All lots  | CGMP Deviations: products may be contaminated with bacteria. | Shadow Holdings DBA Bocchi Labs |



| Product Type | Product Description   | Classification | Code Info   | Reason for Recall  | Recalling Firm                               |
|--------------|---|----------------|---|--|--|
|              | per box,<br>Distributed by:<br>United Exchange Corp., 17311 Valley View Blvd, Cerritos CA 90703 USA, UPC 7 80707 73114 7.   |                |   |  |  |
| Drugs        | READYFLUSH PROTECT with Dimethicone (3.2%), Flushable Personal Cleaning Cloths, 24-count flexible pack. Manufactured by Medline Industries, Inc. Mundelein, IL 60060 USA. NDC 53329-066-58. | Class II       | Lot #<br>18BE0005,<br>18BE0006,<br>Exp.<br>02/2020  | Microbial Contamination of a Non-Sterile Product.  | Medline Industries Inc (Northpoint Services) |
| Drugs        | Option Systems Antibacterial Foaming Hand Wash with .3% PCMX, 1000 mL pouches, Inopak, LTD, Ringwood, NJ  | Class II       | 7302 01 039, 7302 03 039, 7302 01 040 and 7302 01 043   | Microbial contamination of NonSterile Product; FDA analysis returned out of specification results for total aerobic microbial counts | Inopak Ltd                                   |
| Drugs        | HYDROMORPHONE HCl 0.5 mg per mL in 0.9% Sodium Chloride, 1 mL Total Volume in 3 mL syringe, Rx, PharMEDium Services, LLC, Dayton, NJ  | Class II       | Lot numbers:<br>180820005 D, exp 6/21/2018;<br>180990007 D, exp 7/8/2018;<br>and<br>181000020 D, exp 7/9/2018 | Superpotent and Subpotent  | PharMEDium Services, LLC                     |
| Drugs        | Monsel's Solution (Ferric Subsulfate), 20%, packaged as 12 single application   | Class II       | All lots within expiry  | CGMP Deviations: Products not manufactured under current good manufacturing practices.   | BioDiagnostic International                  |

| Product Type | Product Description  | Classification | Code Info   | Reason for Recall               | Recalling Firm            |
|--------------|--|----------------|---|---------------------------------|---------------------------|
|              | vials and 12 applicators, 8 mL per box, Manufactured For: MedGyn Products, Inc., 100 W. Industrial Rd., Addison, IL 60101 USA; Manufactured By: BioDiagnostics Intl, 555 West Lambert Road Unit-C, Brea, CA 92821, NDC 42721-112-08. |                |   |                                 |                           |
| Drugs        | Lidocaine Patch 5% (700 mg), (NDC 0591-3525-11), 30 envelopes containing 1 patch each/ 30 Patches/ Carton (NDC 0591-3525-30)   | Class III      | Carton Lot Number:114 7020B Patch (Envelope) Lot Number: 1147020              | Failed Stability Specifications | Teva Pharmaceuticals USA  |
| Drugs        | T Shampoo For Hair and Body, Solution Coal Tar 3% (0.6% coal tar), 300 ml/10.1 fl. oz. bottles, Dermatologic Cosmetic Laboratories, East Haven, CT   | Class III      | Lot # MT390-8, expiration date 12/01/2020 GU925-4, expiration date 07/05/2020 | Subpotent                       | Milbar Laboratories, Inc. |
| Drugs        | Zoma Shampoo, Zinc Pyrithione 1.92%, 300 ml/10.01 fl. oz. bottles, Dermatologic Cosmetic Laboratories, East Haven, CT  | Class III      | Lot # HT659-6, expiration date 08/11/2019 LT168-7, expiration date 11/10/2019 | Subpotent                       | Milbar Laboratories, Inc. |
| Drugs        | Hydrocodone  | Class III      | Lot #   | Labeling: Missing Label         | LUPIN                     |

| Product Type | Product Description   | Classification | Code Info  | Reason for Recall   | Recalling Firm                         |
|--------------|---|----------------|--|---|--|
|              | <p>Bitartrate and Acetaminophen Tablets, USP, 5 mg/325 mg, 1000-count bottle Rx Only,<br/>                     Manufactured by:<br/>                     Novel Laboratories, Inc. Somerset NJ 08873<br/>                     Manufactured for:<br/>                     Lupin Pharmaceuticals, Inc. Baltimore, MD 212020 NDC 43386-356-10<br/>                     UPC 343386356102</p> |                | S800257;<br>Exp. 01/20   |   | SOMERSET                               |
| Drugs        | <p>Valsartan Tablets USP, 320 mg, 90 tablet, Rx Only,<br/>                     Manufactured by:<br/>                     Jubilant Generics Ltd. Roorkee - 247661, India,<br/>                     Marketed by:<br/>                     Jubilant Cadista Pharmaceuticals, Inc., Salisbury, MD 21801, NDC 59746-363-90</p>   | Class III      | <p>Lot #:<br/>                     VR417065A,<br/>                     VR417066A,<br/>                     Exp 10/2019</p> | <p>Incorrect/Undeclared excipient: Product batches were released into commercial distribution with a larger size grade of excipient (Crospovidone).</p> | Jubilant Cadista Pharmaceuticals, Inc. |
| Drugs        | <p>Nystatin Oral Suspension, USP, 500,000 units/5 mL, For Institutional Use Only, packaged in 5 mL cups, Rx Only,<br/>                     Pharmaceutical Associates, Inc. Greenville, SC 29605, NDC 0121-4810-05</p>   | Class III      | <p>Lot: B5B8<br/>                     Exp. 07/2019</p>   | <p>Resuspension problems: Out of specification for appearance and resuspendability.</p>   | Pharmaceutical Associates Inc          |

| Product Type | Product Description   | Classification     | Code Info  | Reason for Recall  | Recalling Firm             |
|--------------|---|--------------------|--|--|----------------------------|
| Drugs        | Maxzide-25 (Triamterene and hydrochlorothiazide) tablets, USP, 37.5 mg/ 25 mg, 100-count bottle, Rx only, Mylan Pharmaceuticals Inc., Morgantown, WV 26505, NDC 0378-0464-01  | Class III          | Lot #: 3087136, Exp 5/20   | Superpotent Drug: Composite assay results obtained during routine stability testing were slightly above specification. | Mylan Pharmaceuticals Inc. |
| Drugs        | Naloxone Hydrochloride Injection, USP, 0.4 mg/mL, 1 mL in 2.5 mL Carpuject Single-use cartridge syringe, Single unit (NDC 0409-1782-03) and 10 count box (NDC 0409-1782-69), Rx Only, Hospira Inc., Lake Forest, IL | Not Yet Classified | 72680LL, Exp. 1DEC2018 (NDC 0409-1782-03); 76510LL, Exp. 1APR2019 (NDC 0409-1782-69) | Presence of Particulate Matter; Potential for particulate matter on the syringe plunger.                               | HOSPIRA INC, LAKE FOREST   |

## CURRENT DRUG SHORTAGES

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### Lorazepam Injection

May 22, 2018

#### Reason for the Shortage

- Bedford discontinued lorazepam injection in May, 2011.
- West-Ward has product on shortage due to manufacturing delays.
- Pfizer has product on shortage due to increased demand and manufacturing delays. Pfizer discontinued 4 mg/mL 10 mL vials in December 2017.
- Akorn has not provided a reason for the shortage.
- Amphastar has product available.

#### Estimated Resupply Dates

- Pfizer has lorazepam 2 mg/mL 1 mL Carpuject syringes on back order and the company cannot estimate a release date. The 2 mg/mL 10 mL vials are on back order and the company estimates a release date of June 2018. The 4 mg/mL 1 mL vials are on back order and the company estimates a release date of June 2018. The 4 mg/mL 1 mL Carpuject syringes are on back order and the company estimates a release date of 2019.
- West-Ward has lorazepam 2 mg/mL 1 mL vials on allocation. The 2 mg/mL 10 mL vials are on back order and the company estimates a release date of June 2018. The 4 mg/mL 1 mL and 10 mL vials are on back order and the company estimates a release date of June to July 2018.
- West-Ward has Ativan 2 mg/mL 1 mL and 10 mL vials on back order and the company estimates a release date of June to July 2018. Ativan 4 mg/mL 1 mL and 10 mL vials are on back order and the company estimates a release date of June 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=87>

### Labetalol Injection

May 22, 2018

#### Reason for the Shortage

- Akorn has labetalol injection available.
- Alvogen has labetalol injection available.
- Pfizer has labetalol injection on shortage due to manufacturing delays.
- West-Ward has labetalol injection available.

#### Estimated Resupply Dates

- Pfizer has labetalol 5 mg/mL 4 mL syringes on back order and the company cannot estimate a release date.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=286>

### 14.6% Sodium Chloride Concentrated Solution for Injection

May 22, 2018

#### Reason for the Shortage

- Pfizer has 14.6% sodium chloride concentrated solution for injection on shortage due to manufacturing delays.

## Estimated Resupply Dates

- Pfizer has 14.6% sodium chloride concentrated solution for injection 20 mL and 40 mL vials on back order and the company estimates a release date of June 2018.
- Fresenius Kabi has 14.6% sodium chloride concentrated solution for injection 40 mL vials available with an expiration date of < 3 months.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=416>

## Penicillamine

**May 23, 2018**

### Reason for the Shortage

- Mylan did not provide a reason for the shortage.

## Estimated Resupply Dates

- Mylan has Depen tablets available for emergency drop shipment only.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=379>

## Mitoxantrone Hydrochloride Injection

**May 23, 2018**

### Reason for the Shortage

- Fresenius Kabi has mitoxantrone available.
- Pfizer has mitoxantrone injection on shortage due to manufacturing delays.
- Teva has mitoxantrone injection available except for the 10 mL vials which are temporarily discontinued.

## Estimated Resupply Dates

- Pfizer has mitoxantrone 2 mg/mL 10 mL vials on back order and the company estimates a release date of July 2018.
- Teva has temporarily discontinued mitoxantrone 10 mL vials and the company cannot estimate a release date.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=189>

## Metoclopramide Injection

**May 23, 2018**

### Reason for the Shortage

- Pfizer has metoclopramide injection on shortage due to manufacturing delays.
- Teva has metoclopramide injection on shortage due to increased demand.
- Fresenius Kabi has metoclopramide injection on shortage due to increased demand.

## Estimated Resupply Dates

- Pfizer has metoclopramide 5 mg/mL 2 mL vials available in limited supply.
- Teva has metoclopramide 5 mg/mL 2 mL vials on allocation.
- Fresenius Kabi has metoclopramide 5 mg/mL 2 mL syringes on back order and the company estimates a release date of mid-September 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=338>

## Mannitol Injection

May 23, 2018

### Reason for the Shortage

- American Regent did not provide a reason for the mannitol shortage.
- Baxter did not provide a reason for the mannitol shortage.
- Fresenius Kabi had mannitol on shortage due to increased demand.
- Pfizer has mannitol on shortage due to manufacturing delays.

### Estimated Resupply Dates

- American Regent has mannitol 250 mg/mL 50 mL vials on back order and the company cannot estimate a release date.
- Pfizer has mannitol 250 mg/mL 50 mL vials on back order and the company estimates a release date of July 2018.
- BBraun has mannitol 200 mg/mL 250 mL and 500 mL premixed bags on allocation to current customers.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=341>

## Iron Dextran Injection

May 23, 2018

### Reason for the Shortage

- Allergan has INFED on shortage due to manufacturing delays.
- American Regent discontinued Dexferrum injection in 2014.

### Estimated Resupply Dates

- Allergan has INFED 50 mg/mL 2 mL vials on back order and the company estimates a release date of mid-June 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=408>

## Granisetron Hydrochloride Injection

May 23, 2018

### Reason for the Shortage

- Akorn did not provide a reason for the shortage.
- Fresenius Kabi did not provide a reason for the shortage.
- West-Ward did not provide a reason for the shortage.

### Estimated Resupply Dates

- Akorn has granisetron injection on allocation.
- Fresenius Kabi has granisetron injection 1 mg/mL 1 mL vials on back order and the company estimates a release date in early-July 2018.
- West-Ward has granisetron injection 1 mg/mL 1 mL vials on back order and the company estimates a release date in June to July 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=428>

## Fomepizole Injection

May 23, 2018

### Reason for the Shortage

- Mylan Institutional did not provide a reason for the shortage.
- X-Gen has fomepizole on shortage due to increased demand.

### Estimated Resupply Dates

- X-Gen has fomepizole 1 gram/mL 1.5 mL vials on back order and the company cannot estimate a release date.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=394>

## Ceftriaxone Sodium Injection

May 23, 2018

### Reason for the Shortage

- Apotex has ceftriaxone available.
- Fresenius Kabi states the reason for the shortage is increased demand.
- Pfizer has ceftriaxone injection on shortage due to increased demand and manufacturing delays.
- Sagent states the reason for the shortage is manufacturing delay.
- Sandoz has most ceftriaxone presentations available.
- West-Ward states the reason for the shortage is manufacturing delay.
- Wockhardt relaunched their ceftriaxone presentations in October 2017.

### Estimated Resupply Dates

- Fresenius Kabi has ceftriaxone 2 gram vials available with a short expiration date (< 9 months).
- Lupin has all ceftriaxone presentations on allocation.
- Pfizer has ceftriaxone 500 mg vials, 1 gram ADD-Vantage vials, 2 gram vials, and 2 gram ADD-Vantage vials on allocation.
- Sagent has ceftriaxone 1 gram, 2 gram, and 10 gram vials on back order and the company estimates a release date of June 2018.
- Wockhardt has all ceftriaxone presentations on back order and the company cannot estimate a release date.
- West-Ward has ceftriaxone 500 mg vials on back order and the company cannot estimate a release date. The 2 gram vials are also on allocation.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=86>

## Aminocaproic Acid Injection

May 23, 2018

### Reason for the Shortage

- Pfizer has aminocaproic acid on shortage due to manufacturing delays. [1]

### Estimated Resupply Dates

- Pfizer has aminocaproic acid 250 mg/mL 20 mL vials available in limited supply.[1]

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=346>



## Vancomycin Hydrochloride Injection

May 24, 2018

### Reason for the Shortage

- Athenex has vancomycin injection available.
- Pfizer has vancomycin vials on back order due to manufacturing delays.
- Fresenius Kabi has vancomycin injection on shortage due to increased demand.
- Mylan Institutional has vancomycin injection available.
- Sagent has vancomycin injection on shortage due to manufacturing delays and increased demand.
- Baxter has vancomycin injection available.
- Samson Medical Technologies has vancomycin injection available.

### Estimated Resupply Dates

- Fresenius Kabi has vancomycin 750 mg, 5 gram and 10 gram vials on intermittent back order with regular releases.
- Pfizer has vancomycin 500 mg vials, 500 mg ADD-Vantage vials, 750 mg vials, 750 mg ADD-Vantage vials, 1 gram vials, 1 gram ADD-Vantage vials, 5 gram vials, and 10 gram vials available for direct orders only.
- Sagent has vancomycin 5 gram vials on allocation. The 10 gram vials are on back order and the company estimates a release date of July 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=25>

## Thiothixene Capsules

May 24, 2018

### Reason for the Shortage

- Mylan did not provide a reason for the shortage.
- Mylan is the sole supplier of thiothixene.

### Estimated Resupply Dates

- Mylan has thiothixene 1 mg, 2 mg, 5 mg, and 10 mg capsules in 100 count bottles on back order and the company estimates a release date of mid-June 2018.
- Mylan Institutional has thiothixene 2 mg, 5 mg, and 10 mg capsules in 100 count unit-dose blister packs on back order and the company estimates a release date of early-July 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=418>

## Selenium Injection (As Selenious Acid)

May 24, 2018

### Reason for the Shortage

- American Regent did not provide a reason for the shortage.

### Estimated Resupply Dates

- American Regent has selenium 40 mcg/mL 10 mL vials available in limited supply.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=308>

## Pamidronate Disodium Solution for Injection

May 24, 2018

### Reason for the Shortage

- Mylan Institutional did not provide a reason for the shortage.
- Pfizer has pamidronate on shortage due to manufacturing delays.

### Estimated Resupply Dates

- Mylan Institutional has pamidronate 3 mg/mL and 9 mg/mL 10 mL vials on back order and the company estimates a release date of early-August 2018.
- Pfizer has pamidronate 3 mg/mL 10 mL vials and 9 mg/mL 10 mL vials on back order and the company estimates a release date of June 2018. The 6 mg/mL 10 mL vials are available in limited supply.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=402>

## Methylene Blue

May 24, 2018

### Reason for the Shortage

- Akorn has methylene blue on shortage due to manufacturing delays.
- American Regent has recently launched an FDA approved presentation, ProvayBlue and product is available.

### Estimated Resupply Dates

- Akorn has methylene blue 10 mg/mL 1 mL and 10 mL vials on back order and the company cannot estimate a release date.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=47>

## Diltiazem Hydrochloride Injection

May 24, 2018

### Reason for the Shortage

- Akorn states the reason for the shortage was increased demand due to market conditions.
- Pfizer states the reasons for the shortage is manufacturing delays and increases in demand.
- West-Ward has diltiazem injection on shortage due to manufacturing delays caused by increased demand due to current market conditions.

### Estimated Resupply Dates

- Akorn has diltiazem 5 mg/mL 5 mL and 10 mL vials on intermittent back order and is allocating product upon release. The 25 mL vials in 1 count and 10 count are on intermittent back order and the company is allocating product upon release.
- Pfizer has 100 mg ADD-Vantage vials available in limited supply. The 5 mg/mL 5 mL and 10 mL vials are on back order and the company estimates a release date of 2019.
- West-Ward has diltiazem 5 mg/mL 5 mL, 10 mL, and 25 mL vials on allocation.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=26>

## Thiamine Injection

May 25, 2018

### Reason for the Shortage

- Fresenius Kabi had thiamine injection on shortage due to short-term manufacturing delays.
- Mylan Institutional did not provide a reason for the shortage.

### Estimated Resupply Dates

- All marketed presentations are available.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=387>

## Metronidazole Hydrochloride Injection

May 25, 2018

### Reason for the Shortage

- Pfizer has metronidazole injection on shortage due to manufacturing delay.
- BBraun did not provide a reason for the metronidazole injection shortage.

### Estimated Resupply Dates

- BBraun has metronidazole 100 mL bags on allocation to current customers.
- Pfizer has metronidazole 100 mL bags in 24 count and 80 count on back order and the company estimates a release date of June 2018 for the 24 count and July 2018 for the 80 count.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=316>

## Metoprolol Injection

May 25, 2018

### Reason for the Shortage

- Alvogen has metoprolol injection available.[1]
- American Regent has had metoprolol injection on long-term back order for several years.[2]
- Athenex has metoprolol injection available.[3]
- Claris did not provide a reason for the shortage.[4]
- Fresenius Kabi has metoprolol injection on shortage due to increased demand.[5]
- Mylan Institutional acquired metoprolol injection from Sagent. They discontinued metoprolol injection in March 2018.[6]
- Pfizer has metoprolol injection on shortage due to manufacturing delays.[7]
- West-Ward has metoprolol injection available.[8]

### Estimated Resupply Dates

- Baxter (formerly Claris) has metoprolol 1 mg/mL 5 mL vials on back order and the company cannot estimate a release date.[4]
- Fresenius Kabi has metoprolol 1 mg/mL 5 mL vials on back order and the company estimates a release date of late-June 2018.[5]
- Pfizer has metoprolol 1 mg/mL 5 mL ampules and 1 mg/mL 5 mL Carpuject syringes on back order and the company estimates a release date of 2019.[7]
- West-Ward has metoprolol 1 mg/mL 5 mL vials on allocation.[8]

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=363>

## Methylphenidate Extended-Release Oral Suspension and Chewable Tablets

May 25, 2018

### Reason for the Shortage

- Pfizer has Quillivant XR on shortage due to manufacturing delays.
- Pfizer has QuillChew ER chewable tablets available.

### Estimated Resupply Dates

- Pfizer has Quillivant XR 5 mg/mL extended-release oral suspension in 60 mL bottles on back order and the company estimates a release date of July 2018. The QuilliChews 20 mg chewable tablets are on back order and the company estimates a release date of late-June 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=373>

## Erythromycin Lactobionate Injection

May 25, 2018

### Reason for the Shortage

- Pfizer has Erythrocin on shortage due to manufacturing delays.

### Estimated Resupply Dates

- Pfizer has Erythrocin 500 mg vials and 500 mg ADD-Vantage vials on back order and the company estimates a release date of 2019.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=247>

## Dexamethasone Sodium Phosphate Injection

May 25, 2018

### Reason for the Shortage

- American Regent has dexamethasone sodium phosphate on shortage due to manufacturing delays.
- AuroMedics has dexamethasone sodium phosphate on intermittent back order.
- Fresenius Kabi has dexamethasone sodium phosphate presentations available.
- Mylan Institutional did not provide a reason for the shortage.
- West-Ward has dexamethasone sodium phosphate available.

### Estimated Resupply Dates

- American Regent has dexamethasone sodium phosphate 4 mg/mL products on back order and the company cannot estimate a release date.
- AuroMedics has dexamethasone sodium phosphate 4 mg/mL 1 mL vials on intermittent back order and the company is releasing product as it becomes available.
- Fresenius Kabi has dexamethasone sodium phosphate 4 mg/mL 1 mL prefilled syringes on back order and the company estimates a release date of 4th quarter 2018.
- Mylan Institutional has dexamethasone 4 mg/mL 1 mL and 5 mL vials on back order and the company estimates a release date of late-June 2018.
- West-Ward has dexamethasone sodium phosphate 4 mg/mL 1 mL and 5 mL vials on back order and the company cannot estimate a release date.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=140>

## Deferoxamine Injection

May 25, 2018

### Reason for the Shortage

- Fresenius Kabi has deferoxamine on shortage due to increased demand.
- Pfizer has deferoxamine on shortage due to manufacturing delays.
- Novartis has Desferal on shortage due to increased demand.

### Estimated Resupply Dates

- Fresenius Kabi has deferoxamine 2 gram vials on back order and the company estimates a release date of mid-June 2018. Check wholesalers for inventory.
- Pfizer has deferoxamine 500 mg and 2 gram vials on back order and the company estimates a release date of 2019. Pfizer has a limited supply of short-dated 2 gram vials.
- Novartis has Desferal 500 mg vials on allocation

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=393>

## Clindamycin Phosphate Injection

May 25, 2018

### Reason for the Shortage

- Akorn did not provide a reason for the shortage.
- Alvogen did not provide a reason for the shortage.
- Fresenius Kabi did not provide a reason for the shortage.
- Pfizer has Cleocin available.
- Sagent had clindamycin on shortage due to manufacturing delays.
- Sandoz has clindamycin injection available.

### Estimated Resupply Dates

- Alvogen has clindamycin 150 mg/mL 2 mL, 4 mL, and 6 mL ADD-Vantage presentations on back order and the company cannot estimate a release date.
- Pfizer has Cleocin 150 mg/mL 2 mL, 4 mL, and 6 mL ADD-Vantage vials on back order and the company estimates a release date of 2019. Cleocin 150 mg/mL 4 mL vials, 900 mg/50 mL in 5% dextrose premixed bags, and 600 mg/50 mL in 5% dextrose premixed bags are available in limited quantities.
- Fresenius Kabi has clindamycin 150 mg/mL 2 mL, 4 mL, 6 mL, and 60 mL vials available with an expiration date of <9 months.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=97>

## Cisplatin Injection

May 25, 2018

### Reason for the Shortage

- Athenex has cisplatin available.
- Fresenius Kabi has cisplatin available.
- Mylan Institutional discontinued cisplatin in January 2018.
- Teva had cisplatin on allocation due to increased demand.
- WG Critical Care has cisplatin available.

## Estimated Resupply Dates

- Fresenius Kabi has cisplatin 1 mg/mL 50 mL vials available with short-expiration dating of <6 months.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=96>

## Calcium Gluconate Injection

**May 25, 2018**

### Reason for the Shortage

- American Regent has calcium gluconate on shortage due to manufacturing delays.
- Fresenius Kabi has calcium gluconate available with alternating short-dating due to manufacturing process of the vials.

## Estimated Resupply Dates

- American Regent has calcium gluconate 100 mg/mL 50 mL and 100 mL vials on back order and the company cannot estimate a release date.
- Fresenius Kabi has calcium gluconate 100 mg/mL 10 mL, 50 mL, and 100 mL vials on back order and the company estimates a release date of mid-June 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=150>

## Butorphanol Tartrate Injection

**May 25, 2018**

### Reason for the Shortage

- Pfizer has butorphanol injection on shortage due to manufacturing delays.

## Estimated Resupply Dates

- Pfizer has butorphanol 2 mg/mL 1 mL and 2 mL vials on back order and the company estimates a release date of mid-August 2018 for the 1 mL vials and July 2018 for the 2 mL vials. The 1 mg/mL 1 mL vials are on back order and the company estimates a release date of early-July 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=414>

## Aminophylline Injection

**May 25, 2018**

### Reason for the Shortage

- Pfizer has aminophylline injection on shortage due to manufacturing delays.

## Estimated Resupply Dates

- Pfizer has aminophylline 25 mg/mL 10 mL and 20 mL vials on back order and the company estimates a release date of July 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=407>

## Acetylcysteine Oral and Inhalation Solution

**May 25, 2018**

### Reason for the Shortage

- American Regent has acetylcysteine oral and inhalation solution on shortage due to manufacturing delays.
- Fresenius Kabi has acetylcysteine oral and inhalation solution available.
- Pfizer has acetylcysteine oral and inhalation solution on shortage due to manufacturing delays.
- Roxane Labs discontinued acetylcysteine oral and inhalation solution in April 2014.
- Arbor has Cetylev effervescent tablets available. These are for oral use only.

#### Estimated Resupply Dates

- American Regent has acetylcysteine solution 100 mg/mL 10 mL and 200 mg/mL 10 mL and 30 mL vials on back order and the company cannot estimate a release date.
- Fresenius Kabi has acetylcysteine solution 200 mg/mL 4 mL and 10 mL vials on back order and the company estimates a release date of mid- to late-June 2018. The 100 mg/mL 4 mL, 10 mL and 30 mL vials are on back order and the company estimates a release date of mid- to late-June 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=43>

### Sodium Acetate Injection

**May 28, 2018**

#### Reason for the Shortage

- American Regent has had sodium acetate on long-term back order for several years.
- Fresenius Kabi had sodium acetate on shortage due to increased demand.
- Pfizer has sodium acetate on shortage due to manufacturing delays.

#### Estimated Resupply Dates

- All marketed presentations are available.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=317>

### Mepivacaine Injection

**May 28, 2018**

#### Reason for the Shortage

- Fresenius Kabi has Polocaine and Polocaine-MPF available.
- Pfizer states the reason for the shortage is manufacturing delays.

#### Estimated Resupply Dates

- Fresenius Kabi has 1.5% Polocaine-MPF 30 mL preservative-free vials on back order and the company estimates a release date of late-July to early-August 2018.
- Pfizer has 2% Carbocaine 20 mL preservative-free vials, 1% Carbocaine 30 mL preservative-free vials, and 1.5% Carbocaine 30 mL preservative-free vials on back order and the company estimates a release date of 2019. The 1% Carbocaine 50 mL multiple-dose vials are available in limited supply.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=331>

### Meperidine Hydrochloride Injection

**May 28, 2018**

#### Reason for the Shortage

- Pfizer has Demerol injection on shortage due to manufacturing delays.



## Estimated Resupply Dates

- Pfizer has Demerol 100 mg/mL 20 mL vials and on back order and the company estimates a release date of March 2019. The 25 mg/mL 1 mL Carpuject syringes, 50 mg/mL 1 mL Carpuject syringes, 75 mg/mL 1 mL Carpuject syringes, and 100 mg/mL 1 mL Carpuject syringes are on back order and the company estimates a release date of March 2019. The 50 mg/mL 0.5 mL ampules are on back order and the company estimates a release date of early-August 2018. The 50 mg/mL 1 mL ampules and 30 mL vials are on back order and the company estimates a release date of early-July 2018.
- West-Ward has 25 mg/mL 1 mL vials and 50 mg/mL 1 mL vials on allocation.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=347>

## Tobramycin Sulfate Injection

**May 29, 2018**

### Reason for the Shortage

- Akorn has tobramycin injection on shortage due to manufacturing delays.
- Pfizer did not provide a reason for the shortage.

### Estimated Resupply Dates

- Akorn has tobramycin 40 mg/mL 2 mL and 30 mL vials on back order and the company cannot estimate a release date.
- Baxter (formerly Claris) has tobramycin 40 mg/mL 2 mL and 30 mL vials on back order and the company cannot estimate a release date.
- Mylan Institutional has tobramycin 40 mg/mL 2 mL vials on back order and the company estimates a release date of mid- to late-June 2018.
- Teva has temporarily discontinued tobramycin 40 mg/mL 2 mL vials.
- Fresenius Kabi has tobramycin 1.2 gram powder for injection on back order and the company estimates a release date of mid-June 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=164>

## Isosorbide Dinitrate Extended-Release Tablets

**May 29, 2018**

### Reason for the Shortage

- Sun Pharma is not currently manufacturing isosorbide dinitrate 40 mg extended-release tablets.

### Estimated Resupply Dates

- Sun Pharma has isosorbide dinitrate 40 mg extended-release tablets on long-term back order and the company cannot estimate a release date.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=337>

## Fentanyl Citrate Injection

**May 29, 2018**

### Reason for the Shortage

- Akorn has fentanyl injection on shortage due to increased demand.
- West-Ward has fentanyl injection on shortage due to supply and demand issues.



- Pfizer has fentanyl injection on shortage due to manufacturing delays. The 20 mL ampules were discontinued in September 2017.

#### Estimated Resupply Dates

- Akorn has Sublimaze 50 mcg/mL 2 mL ampules in 10 count and 5 mL ampules in 10 count on intermittent back order and is allocating product upon release. Sublimaze 50 mcg/mL 2 mL ampules in 25 count and 5 mL ampules in 25 count are temporarily not being packaged.
- Pfizer has fentanyl 50 mcg/mL 2 mL on back order and the company estimates a release date of late-June 2018. The 2 mL ampules are available in limited supply. The 2 mL Carpuject syringes are on back order and the company estimates a release date of June 2019. The 2 mL, 5 mL, 10 mL, 20 mL, and 50 mL vials are on back order and the company estimates a release date of mid-June 2018 for the 2 mL vials, late-June 2018 for the 5 mL vials, mid-July 2018 for the 10 mL vials, and early-July 2018 for the 20 mL and 50 mL vials.
- West-Ward has fentanyl 50 mcg/mL 2 mL, 5 mL, and 50 mL vials on allocation. The 20 mL vials are on back order and the company estimates a release date of June 2018. The 2 mL, 5 mL, and 20 mL ampules are on back order and the company cannot estimate a release date.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=315>

### Epinephrine Auto-Injectors

**May 29, 2018**

#### Reason for the Shortage

- Impax was not able to provide a reason for the shortage.
- Mylan has EpiPen on shortage due to supply constraints.

#### Estimated Resupply Dates

- Impax has epinephrine 0.15 mg/0.15 mL and 0.3 mg/0.3 mL auto-injectors on back order and the company cannot estimate a release date.
- Mylan has EpiPen, EpiPen Jr, and their authorized generic presentations on intermittent back order with regular releases.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=420>

### Sincalide Injection

**May 30, 2018**

#### Reason for the Shortage

- Bracco Diagnostics has Kinevac injection on shortage due to a supply disruption.
- There are no approved alternatives to Kinevac for the labeled indications.

#### Estimated Resupply Dates

- Bracco has Kinevac on intermittent backorder and on allocation when available.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=277>

### Multiple Electrolytes Large Volume Solutions for Injection

**May 30, 2018**

#### Reason for the Shortage

- Baxter did not provide a reason for Plasma-Lyte A shortage. Plasma-Lyte 148 is available.
- Pfizer had Normosol-R presentations on back order due to manufacturing delays.

## Estimated Resupply Dates

- Baxter has Plasma-Lyte-A pH 7.4 1000 mL bags on allocation.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=389>

## Methadone Injection

**May 30, 2018**

### Reason for the Shortage

- Akorn did not provide a reason for the shortage.
- Mylan Institutional has methadone injection available.

## Estimated Resupply Dates

- Akorn has methadone injection on allocation.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=358>

## Calcium Chloride Injection

**May 30, 2018**

### Reason for the Shortage

- American Regent has calcium chloride injection available.
- Amphastar has calcium chloride injection available.
- Pfizer has calcium chloride on shortage due to manufacturing delays.
- Mylan Institutional has withdrawn calcium chloride syringes from the market. The company recalled the syringes in April 2015 due to incompatibility of the syringes and some needless adaptors.

## Estimated Resupply Dates

- Pfizer has calcium chloride 100 mg/mL 10 mL Ansyr syringes and 100 mg/mL 10 mL LifeShield syringes on back order and the company estimates a release date of June 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=48>

## Progesterone Injection

**June 1, 2018**

### Reason for the Shortage

- American Regent did not provide a reason for the shortage.
- Fresenius Kabi has progesterone on shortage due to increased demand and manufacturing delays.
- Teva has progesterone on shortage due to supply constraints.
- West-Ward has progesterone on shortage due to manufacturing delays.

## Estimated Resupply Dates

- American Regent has progesterone in oil 50 mg/mL 10 mL vials for intramuscular injection on back order and the company cannot estimate a release date.
- Fresenius Kabi has progesterone in oil 50 mg/mL 10 mL vials for intramuscular injection on back order and the company estimates a release date of early-July 2018.

- Teva has progesterone in oil 50 mg/mL 10 mL vials for intramuscular injection on back order and the company estimates a release date of mid-June 2018.
- West-Ward has progesterone in oil 50 mg/mL 10 mL vials for intramuscular injection on allocation.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=381>

## Sufentanil Injection

**June 4, 2018**

### Reason for the Shortage

- Pfizer has sufentanil injection on shortage due to manufacturing delays.
- Akorn has Sufenta injection on shortage due to increased demand for the product.
- West-Ward did not provide a reason for the shortage.

### Estimated Resupply Dates

- Pfizer has sufentanil 50 mcg/mL 1 mL and 5 mL vials on back order and the company estimates a release date of early-August 2018 for the 1 mL vials and December 2018 for the 5 mL vials.
- Akorn has Sufenta 50 mcg/mL 1 mL and 2 mL ampules on allocation. The 5 mL ampules are on back order and the company estimates a release date of mid-June 2018.
- West-Ward has sufentanil 50 mcg/mL 5 mL ampules available with an expiration date of July 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=376>

## Sterile Water for Injection – Small Volume Vials

**June 4, 2018**

### Reason for the Shortage

- American Regent has limited availability of sterile water for injection.
- Fresenius Kabi has sterile water on shortage due to increased demand.
- Pfizer has sterile water for injection in vials on shortage due to manufacturing delays.

### Estimated Resupply Dates

- American Regent has sterile water for injection 10 mL vials available in limited quantities. Check wholesalers for inventory. The 5 mL vials are on back order and the company cannot estimate a release date.
- Fresenius Kabi has sterile water for injection 5 mL, 10 mL, 20 mL, 50 mL, and 100 mL vials on back order and the company estimates a release date of late-June 2018 for the 5 mL vials, late-June 2018 for the 10 mL vials, late-July to early-August 2018 for the 20 mL vials, mid- to late-June 2018 for the 50 mL vials, and the company could not estimate a release date for the 100 mL vials. Check wholesalers for inventory.
- Pfizer has sterile water for injection 10 mL, 20 mL, 50 mL, and 100 mL vials on back order and the company estimates a release date in June 2018 for the 10 mL and 20 mL vials and July 2018 for the 50 mL and 100 mL vials.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=375>

## Sodium Polystyrene Sulfonate Oral or Rectal Suspension

June 4, 2018

### Reason for the Shortage

- CMP Pharma has SPS Suspension available.
- Perrigo has temporarily discontinued their Kionex suspension and sodium polystyrene sulfonate suspension. They cannot estimate when these products will be manufactured again.
- West-Ward did not provide a reason for the shortage.

### Estimated Resupply Dates

- West-Ward has sodium polystyrene sulfonate suspension in 60 ml and 120 mL bottles on back order and the company cannot estimate a release date.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=430>

## Nalbuphine Injection

June 4, 2018

### Reason for the Shortage

- Pfizer has nalbuphine or shortage due to manufacturing delays.

### Estimated Resupply Dates

- Pfizer has nalbuphine 10 mg/mL 1 mL ampules on back order and the company estimates a release date of July 2018. The 20 mg/mL 1 mL ampules are on back order and the company estimates a release date of mid-July 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=409>

## Leuprolide Acetate 14-Day Kit

June 4, 2018

### Reason for the Shortage

- Sun Pharma did not provide a reason for the shortage.
- Sandoz states the reason for the shortage was increased demand.
- Teva states the shortage is due to manufacturing delays.

### Estimated Resupply Dates

- Sandoz has leuprolide acetate injection on back order and the company estimates a release date of mid-June 2018.
- Teva has leuprolide acetate injection on long-term back order and the company cannot estimate a release date.
- Sun Pharma has leuprolide acetate injection on back order and the company cannot estimate a release date.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=81>

## 5% Dextrose Injection (Pvc-Free and Dehp-Free)

June 4, 2018

### Reason for the Shortage

- ICU Medical states the shortage is due to increased demand and manufacturing delays. ICU Medical discontinued the 500 mL VisIV bags in 2011 due to leaking around the administration and medications ports.
- ICU Medical is now the IV fluid business of Pfizer after the acquisition of Hospira.
- Baxter is not currently marketing 5% dextrose PVC/DEHP-free bags.
- BBraun has 250 mL, 500 mL, and 1,000 mL PVC/DEHP-free bags on back order due to manufacturing delays.

#### Estimated Resupply Dates

- BBraun has 5% dextrose 250 mL, 500 mL, and 1,000 mL PVC/DEHP-free bags on allocation to current customers.
- ICU Medical has 5% dextrose in 50 mL PVC/DEHP-free bags on back order and the company estimates a release date in late-July 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=314>

### 0.9% Sodium Chloride Small Volume Bags (<150mL)

**June 4, 2018**

#### Reason for the Shortage

- Baxter has 0.9% sodium chloride small volume bags on shortage due to manufacturing delays.
- BBraun has 0.9% sodium chloride small volume bags on shortage due to increased demand.
- ICU Medical has 0.9% sodium chloride small volume bags on shortage due to increased demand.

#### Estimated Resupply Dates

- Baxter has all 0.9% sodium chloride small volume bags on allocation.
- BBraun has all 0.9% sodium chloride small volume bags on allocation to current customers only.
- Pfizer has 0.9% sodium chloride 50 mL Add-Vantage bags and 100 mL Add-Vantage bags on back order and the company estimates a release date in June 2018. The 50 mL preservative-free vials are on intermittent back order and the company is releasing supplies as they become available.
- ICU Medical has the 0.9% sodium chloride 50 mL VisIV bags, 50 mL bags, and 100 mL VisIV bags on intermittent back order and the company is releasing supplies as they become available. The 100 mL bags in 48 and 80 count are on allocation.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=352>

### 0.9% Sodium Chloride 10mL, 20mL, and 50mL Preservative Free Vials and Syringes

**June 4, 2018**

#### Reason for the Shortage

- Fresenius Kabi did not provide a reason for the shortage.
- Pfizer has 0.9% sodium chloride preservative-free vials on shortage due to manufacturing delays.

#### Estimated Resupply Dates

- Fresenius Kabi has 0.9% sodium chloride preservative free 10 mL and 20 mL vials on back order and the company estimates a release date of mid-June 2018 for the 10 mL vials and mid- to late-June 2018 for the 20 mL vials.
- Pfizer has 0.9% sodium chloride preservative free 10 mL LifeShield syringes on back order and the company estimates a release date of June 2018. The 10 mL and 20 mL vials are on back

order and the company estimates a release date of June 2018. The 50 mL vials are on back order and the company cannot estimate a release date.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=332>

## Sodium Bicarbonate Injection

June 5, 2018

### Reason for the Shortage

- Amphastar has sodium bicarbonate injection available.
- Pfizer has sodium bicarbonate injection on shortage due to manufacturing delays.
- Fresenius Kabi has reintroduced sodium bicarbonate injection in response to the shortage.

### Estimated Resupply Dates

- Pfizer has sodium bicarbonate 4.2% 10 mL LifeSheid syringes on back order and the company estimates a release date of August 2018. The 8.4% 10 mL syringes are available.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=293>

## Potassium Chloride Injection

June 5, 2018

### Reason for the Shortage

- Baxter has their highly concentrated potassium chloride in sterile water on shortage because a manufacturing facility has been affected by Hurricane Maria. Baxter has removed these products from distribution and they can be purchased directly if they are in stock. Baxter is also adjusting the allocation of these products. Baxter did not provide a reason for the shortage of their other potassium chloride products.
- Fresenius Kabi did not provide a reason for the shortage.
- Pfizer has potassium chloride injection on shortage due to increase demand and manufacturing delays. Pfizer discontinued 2 mEq/mL 250 mL bottles in mid-2018.
- ICU Medical has potassium chloride injection on shortage due to increased demand.
- ICU Medical discontinued potassium chloride 10 mEq/500 mL in 5% dextrose and 0.225% sodium chloride in 2018.

### Estimated Resupply Dates

- Baxter has potassium chloride 20 mEq/1000 mL in lactated ringer's and 5% dextrose on back order and the company cannot estimate a release date.
- Baxter has potassium chloride 40 mEq/100 mL and 20 mEq/50 mL in sterile water bags on back order and the company cannot estimate a release date.
- Fresenius Kabi has potassium chloride 10 mEq/5 mL, 20 mEq/10 mL, 40 mEq/20 mL, and 60 mEq/30 mL vials on back order and the company estimates a release date of mid-July 2018 for the 5 mL vials and 20 mL vials and early-July 2018 for the 10 mL and 30 mL vials.
- ICU Medical has potassium chloride 20 mEq/1000 mL in 0.9% sodium chloride available in limited supply. Potassium chloride 10 mEq/500 mL in 5% dextrose and 0.45% sodium chloride is on back order and the company estimates a release date of early-September 2018.
- Pfizer has potassium chloride 10 mEq/5 mL vials, 20 mEq/10 mL vials, and 40 mEq/20 mL vials on back order and the company estimates a release date of August 2018 for the 5 mL vials and July 2018 for the 10 mL and 20 mL vials.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=12>

## Nitrofurantoin Oral Suspension

June 5, 2018

### Reason for the Shortage

- Amneal did not provide a reason for the shortage.
- Casper Pharma and Lupin Pharmaceuticals were not available to provide information.
- Nostrum did not provide a reason for the shortage.
- Teva did not provide a reason for the shortage.

### Estimated Resupply Dates

- Amneal has nitrofurantoin oral suspension on back order and the company cannot estimate a release date.
- Nostrum has nitrofurantoin oral suspension on back order and the company cannot estimate a release date.
- Teva has nitrofurantoin oral suspension on back order and the company estimates a release date in late-June 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=433>

## Ketorolac Injection

June 5, 2018

### Reason for the Shortage

- Alvogen has ketorolac injection available in 25 count sizes.
- Amphastar did not provide a reason for the shortage.
- Athenex has ketorolac injection available.
- BD RX is now part of Fresenius Kabi.
- Fresenius Kabi has ketorolac available.
- Pfizer has ketorolac injection on back order due to manufacturing delays.
- Sagent states the reason for the shortage is manufacturing delay.
- West-Ward did not provide a reason for the shortage.
- Ben Venue closed its plant in Bedford, Ohio in July 2014.
- Virtus has ketorolac injection available.
- FDA imposed an import ban in mid-2013 on several Wockhardt products including ketorolac.
- Sprix Nasal Spray is not affected by this shortage.

### Estimated Resupply Dates

- Alvogen has 15 mg/mL 1 mL vials and 30 mg/mL 1 mL vials on back order with unknown release dates.<sup>1</sup>
- Amphastar has ketorolac 30 mg/mL 1 mL vials on back order and the company cannot estimate a release date.
- Pfizer has ketorolac 15 mg/mL 1 mL vials available in limited supply. The 30 mg/mL 1 mL Carpuject syringes, 30 mg/mL 2 mL Carpuject syringes for intramuscular injection, and 30 mg/mL 1 mL iSecure syringes are on back order and the company estimates a release date of 2019.
- Sagent has all ketorolac products on back order. The company estimates release dates of July 2018 for the 30 mg/mL 2 mL vials for intramuscular injection and June 2018 for the 15 mg/mL 1 mL vials and 30 mg/mL 1 mL vials.



- West-Ward has ketorolac 15 mg/mL 1 mL vials on back order and the company estimates a release date of June to July 2018. The 30 mg/mL 1 mL vials and 30 mg/mL 2 mL vials for intramuscular injection are on allocation.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=113>

## Fluorouracil Injection

June 5, 2018

### Reason for the Shortage

- Accord did not provide a reason for the shortage.
- Fresenius Kabi did not provide a reason for the shortage.
- Teva has fluorouracil injection on allocation due to increased demand.

### Estimated Resupply Dates

- Accord had fluorouracil 50 mg/mL 10 mL and 100 mL vials on back order and the company estimates release dates of early-June 2018. The 20 mL and 50 mL vials are on back order and the company estimates release dates of mid-June 2018.
- Fresenius Kabi has fluorouracil 50 mg/mL 10 mL, 20 mL, 50 mL, and 100 mL vials on back order and the company estimates release dates of early-June 2018 for the 10 mL, 20 mL, and 100 mL vials, and mid-June 2018 for the 50 mL vials.
- Teva has Adrucil 50 mg/mL 10 mL, 50 mL, and 100 mL vials on allocation.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=401>

## Cefazolin Injection

June 5, 2018

### Reason for the Shortage

- Apotex has discontinued all presentations except cefazolin 10 gram vials. The 10 gram vials are not currently being manufactured.
- Baxter did not provide a reason for the shortage.
- BBraun did not provide a reason for the shortage.
- Fresenius Kabi has most cefazolin products available.
- Pfizer states the reason for the shortage is manufacturing delay.
- Sagent states the reason for the shortage is manufacturing delays and increased demand.
- Samson Medical Technologies has cefazolin injection available.
- Sandoz has cefazolin injection available.
- West-Ward did not provide a reason for the shortage.
- WG Critical Care did not provide a reason for the shortage.

### Estimated Resupply Dates

- Baxter has cefazolin 2 gram/100 mL premixed bags on allocation.
- BBraun has 1 gram/50 mL and 2 gram/50 mL premixed bags on allocation.
- Fresenius Kabi has cefazolin 20 gram bulk vials on back order and the company cannot estimate a release date.
- Pfizer has 1 gram and 10 gram vials on back order and the company estimates a release date in July 2018.
- Sagent has cefazolin 1 gram and 10 gram vials on back order and the company estimates a release date in August 2018 for the 1 gram vials and June 2018 for the 10 gram vials.



- West-Ward has cefazolin 500 mg vials on back order and the company estimates a release date in June 2018. The 1 gram vials are on allocation.
- WG Critical Care has cefazolin 500 mg vials on back order and the company estimates a release date in late-June 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=432>

## Sterile Water for injection – Large Volume Bags

**June 6, 2018**

### Reason for the Shortage

- Baxter has sterile water for injection on shortage due to manufacturing delays.
- BBraun did not provide a reason for the shortage.
- ICU Medical has sterile water for injection on shortage due to increased demand.

### Estimated Resupply Dates

- Baxter has sterile water for injection presentations on allocation.
- BBraun has sterile water for injection 250 mL, 500 mL, 1000 mL, and 3000 mL bags on allocation to current customers.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=368>

## Rocuronium Injection

**June 6, 2018**

### Reason for the Shortage

- Fresenius Kabi has rocuronium on shortage due to delay of raw materials.
- Pfizer has rocuronium on shortage due to manufacturing delays.
- Sagent has rocuronium on shortage due to increased demand.
- AuroMedics launched rocuronium in mid-2017.

### Estimated Resupply Dates

- AuroMedics has rocuronium 10 mg/mL 5 mL and 10 mL vials available with intermittent releases.
- Sagent has rocuronium 10 mg/mL 5 mL and 10 mL vials on back order and the company estimates a release date of June 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=290>

## Phenytoin Sodium

**June 6, 2018**

### Reason for the Shortage

- West-Ward did not provide a reason for this shortage.
- X-Gen Pharmaceuticals discontinued their phenytoin sodium presentations in April 2017.

### Estimated Resupply Dates

- West-Ward has phenytoin sodium 250 mg/5 mL vials on allocation.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=406>

## Oxacillin Sodium Injection

June 6, 2018

### Reason for the Shortage

- AuroMedics did not provide a reason for the shortage.
- Baxter had oxacillin on shortage due to manufacturing delays.
- Sagent has oxacillin on shortage due to manufacturing delays.

### Estimated Resupply Dates

- AuroMedics has all oxacillin presentations on long-term back order and the company cannot estimate a release date.
- Sagent has oxacillin 1 gram vials on back order and the company estimates a release date of June 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=377>

## Ondansetron Hydrochloride Injection

June 6, 2018

### Reason for the Shortage

- Apotex did not provide a reason for the shortage.
- Athenex has ondansetron injection on shortage due to increased demand.
- AuroMedics did not provide a reason for the shortage.
- Fresenius Kabi has ondansetron injection available.
- Heritage has ondansetron on shortage due to increased demand.
- Mylan Institutional did not provide a reason for the shortage.
- Pfizer has ondansetron injection on shortage due to manufacturing delays.
- Sagent has ondansetron injection on shortage due to manufacturing delays.
- West-Ward did not provide a reason for the shortage.
- Novartis discontinued Zofran 20 mL vials in May 2018.

### Estimated Resupply Dates

- Apotex has ondansetron 2 mg/mL 2 mL vials on back order and the company estimates a release date of early-July 2018.
- Athenex has ondansetron 2 mg/mL 2 mL and 20 mL vials on back order and the company estimates release dates of mid-June to early-July 2018.
- AuroMedics has ondansetron 2 mg/mL 2 mL and 20 mL vials on intermittent back order and the company is releasing product as it becomes available.
- Fresenius Kabi has ondansetron 2 mg/mL 2 mL and 20 mL vials on back order and the company cannot estimate release dates. The 2 mg/mL 2 mL prefilled syringes are on back order and the company estimates a release date of mid-September 2018.
- Heritage has all ondansetron presentations on allocation.
- Mylan Institutional has ondansetron 2 mg/mL 2 mL and 20 mL vials on back order and the company estimates release dates of late-June 2018.
- Pfizer has ondansetron 2 mg/mL 2 mL vials on back order and the company estimates a release date of June 2018. The 2 mg/mL 20 mL vials are on back order and the company estimates a release date of October 2018. The 2 mg/mL 2 mL iSecure syringes are on back order and the company estimates a release date of 2019.

- Sagent has ondansetron 2 mg/mL 2 mL vials on back order and the company estimates a release date of July 2018.
- West-Ward has ondansetron 2 mg/mL 2 mL vials on allocation. The 2 mg/mL 20 mL vials are on back order and the company estimates a release date of early-July to early-August 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=405>

## Moxifloxacin Injection

**June 6, 2018**

### Reason for the Shortage

- Bayer discontinued Avelox IV in December 2017.
- Fresenius Kabi has moxifloxacin injection on shortage due to increased demand.
- Mylan Institutional did not provide a reason for the shortage.

### Estimated Resupply Dates

- Fresenius Kabi has moxifloxacin 400 mg/250 mL premixed bags on back order and the company estimates a release date of late-June 2018.
- Mylan Institutional has moxifloxacin 400 mg/250 mL premixed bags on back order and the company estimates a release date of early-August 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=357>

## Mineral Oil and Petrolatum Ophthalmic Ointment

**June 6, 2018**

### Reason for the Shortage

- Allergan did not provide a reason for the shortage.
- Major did not provide a reason for the shortage.
- Rugby did not provide a reason for the shortage.
- Valeant did not provide a reason for the shortage.

### Estimated Resupply Dates

- Allergan has mineral oil/petrolatum 42.5%/57.3% 3.5 g tubes on back order with an estimated release date of late-June 2018. The company also has 42.5%/56.8% 3.5 g tubes on back order with an estimated release date of late-August 2018 and 7 g tubes on back order with an estimated release date of early October 2018.
- Major has mineral oil/petrolatum 15%/83% 3.5 g tubes on back order and the company cannot estimate a release date.
- Rugby has mineral oil/petrolatum 15%/83% 3.5 g tubes on back order and the company cannot estimate a release date.
- Novartis has mineral oil/petrolatum 15%/85% 3.5 g tubes available.
- Perrigo has mineral oil/petrolatum 15%/85% 3.5 g and 1 g tubes available.
- Valeant has mineral oil/petrolatum 20%/80% 3.5 g tubes on back order with an estimated release date of mid-June 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=435>

## Heparin Injection

June 6, 2018

### Reason for the Shortage

- Fresenius Kabi did not provide a reason for the shortage.
- Pfizer did not provide a reason for the shortage.
- Sagent had heparin on shortage due to manufacturing delay.
- West-Ward did not provide a reason for the shortage.

### Estimated Resupply Dates

- Fresenius Kabi has all presentations available.
- Pfizer has 10,000 unit/mL 0.5 mL Carpuject syringes on back order and the company cannot estimate a release date. The 5,000 unit/mL 1 mL Carpuject syringes are on back order and the company estimates a release date of 2019. The 1,000 unit/mL 10 mL vials are on back order and the company estimates a release date in June 2018. The 10,000 unit/mL 1 mL vials, and 1000 unit/mL 30 mL vials are on back order and the company cannot estimate a release date.
- West-Ward has 1,000 unit/mL 30 mL vials and 5,000 unit/mL 10 mL vials on back order and the company cannot estimate a release date. The 1,000 unit/mL 2 mL vials are on allocation.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=353>

## Famotidine Injection

June 6, 2018

### Reason for the Shortage

- Ben Venue stopped production in its plant in Bedford, Ohio and closed in July 2014.
- West-Ward has famotidine vials available.
- Pfizer launched famotidine injections in March 2012.
- Mylan Institutional acquired famotidine injections from Pfizer on December 6, 2013.
- Fresenius Kabi did not provide a reason for the shortage.
- Baxter has famotidine premixed bags available.

### Estimated Resupply Dates

- Fresenius Kabi has famotidine 2 mL and 4 mL vials on intermittent back order with regular releases. Check wholesalers for inventory.
- Mylan Institutional has famotidine 2 mL, 4 mL, and 20 mL vials on back order and the company estimates a release date of late-July 2018 for the 2 mL vials, mid- to late-June 2018 for the 4 mL vials, and mid-July 2018 for the 20 mL vials.
- West-Ward has famotidine 4 mL and 20 mL vials on back order and the company estimates a release date of late-June to early-July 2018. The 2 mL vials are on allocation.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=166>

## Dorzolamide Ophthalmic Solution

June 6, 2018

### Reason for the Shortage

- Akorn has dorzolamide ophthalmic solution on shortage due to manufacturing delays.
- Merck did not provide a reason for the shortage.
- Sandoz did not provide a reason for the shortage.
- Teva discontinued dorzolamide ophthalmic solution in April 2018.

- Valeant has dorzolamide ophthalmic solution on shortage due to manufacturing delays.

#### Estimated Resupply Dates

- Akorn has dorzolamide 2% ophthalmic solution on allocation.
- Valeant has dorzolamide 2% ophthalmic solution on back order and the company estimates a release date of late-June 2018.
- Sandoz has dorzolamide 2% ophthalmic solution on back order and the company estimates a release date of late-June 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=359>

#### Dorzolamide 2% and Timolol 0.5% Ophthalmic Solution

**June 6, 2018**

#### Reason for the Shortage

- Akorn has dorzolamide and timolol ophthalmic solution on shortage due to manufacturing delays.
- Sandoz did not provide a reason for the shortage.
- Teva discontinued dorzolamide and timolol ophthalmic solution in April 2018.
- Valeant did not provide a reason for the shortage.

#### Estimated Resupply Dates

- Akorn has dorzolamide 2% and timolol 0.5% ophthalmic solution in 10 mL bottles on allocation.
- Valeant has dorzolamide 2% and timolol 0.5% ophthalmic solution in 10 mL bottles on back order and the company estimates a release date of late-June 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=360>

#### Dobutamine Injection

**June 6, 2018**

#### Reason for the Shortage

- Baxter has dobutamine on shortage due to manufacturing delays.
- Pfizer has dobutamine on shortage due to manufacturing delays.

#### Estimated Resupply Dates

- Pfizer has dobutamine 12.5 mg/mL 20 mL and 40 mL latex-free vials on back order with an estimated release date of 2019 for the 20 mL vials and 2018 for the 40 mL vials. The 12.5 mg/mL 20 mL regular vials in 10 count are on back order and the company estimates a release date of July 2018.
- Pfizer has dobutamine 1 mg/mL in 250 mL bags on back order and the company estimates a release date of June 2018. The dobutamine 2 mg/mL 250 mL bags are on back order and the company estimates a release date of June 2018. The dobutamine 4 mg/mL 250 mL bags are on back order and the company estimates a release date of July 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=296>

#### Diclofenac 0.1% Ophthalmic Solution

**June 6, 2018**

#### Reason for the Shortage

- Akorn did not provide a reason for the shortage.
- Rising pharmaceuticals discontinued diclofenac ophthalmic solution.
- Sandoz did not provide a reason for the shortage.

#### Estimated Resupply Dates

- Akorn has diclofenac 0.1% ophthalmic solution on long-term back order.
- Sandoz has diclofenac 0.1% ophthalmic solution in 5 mL bottles on back order and the company estimates a release date of late-June 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=395>

## Cefepime Injection

**June 6, 2018**

#### Reason for the Shortage

- Apotex did not provide a reason for the shortage.
- Baxter had cefepime on shortage due to increased demand.
- BBraun has cefepime on shortage due to increased demand.
- Fresenius Kabi had cefepime injection on shortage due to manufacturing delays.
- Pfizer has Maxipime on shortage due to manufacturing delays.
- Sagent had cefepime injection on shortage due to manufacturing delays.
- Sandoz discontinued cefepime injection in early-2016.
- WG Critical Care had cefepime injection on shortage due to increased demand.

#### Estimated Resupply Dates

- Apotex has cefepime 2 gram vials in 10 count on back order and the company estimates a release date of mid-June 2018.
- BBraun has cefepime 1 gram and 2 gram premixed bags on allocation to current customers.
- Pfizer has Maxipime 1 gram vials, 2 gram vials, 1 gram ADD-Vantage vials, and 2 gram ADD-Vantage vials on back order and the company estimates a release date of 2019.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=59>

## Amiodarone Injection

**June 6, 2018**

#### Reason for the Shortage

- Baxter had Nexterone premixed bags on shortage due to manufacturing delays.
- Mylan Institutional did not provide a reason for the shortage.
- West-Ward did not provide a reason for the shortage.

#### Estimated Resupply Dates

- Mylan Institutional has amiodarone 50 mg/mL 9 mL vials available that expire February 28, 2019. Amiodarone 50 mg/mL 3 mL vials are on back order and the company estimates a release date of late-June 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=374>

## Ropivacaine Injection

June 7, 2018

### Reason for the Shortage

- Akorn has ropivacaine on shortage due to increased demand.
- AuroMedics did not provide a reason for the shortage.
- Fresenius Kabi has Naropin on shortage due to increased demand and manufacturing delays.
- Pfizer has ropivacaine on shortage due to manufacturing delays.

### Estimated Resupply Dates

- Akorn has ropivacaine 2 mg/mL 30 mL vials on allocation.
- AuroMedics has ropivacaine 2 mg/mL 20 mL vials and 100 mL bottles, 7.5 mg/mL 20 mL vials, and 10 mg/mL 10 mL and 20 mL vials on intermittent back order and the company is releasing product as it becomes available.
- Pfizer has ropivacaine 2 mg/mL 10 mL and 20 mL vials on back order and the company estimates a release date of September 2018 for the 10 mL vials and June 2018 for the 20 mL vials. The 5 mg/mL 30 mL vials are on back order and the company estimates a release date of June 2018. The 7.5 mg/mL 20 mL vials are on back order and the company estimates a release date of July 2018. The 10 mg/mL 10 mL and 20 mL vials are on back order and the company estimates a release date of September 2018 for the 10 mL vials and June 2018 for the 20 mL vials.
- Fresenius Kabi has Naropin 2 mg/mL 100 mL and 200 mL bottles on back order and the company estimates a release date of mid-June 2018. The 2 mg/mL 200 mL premixed bags are on back order and the company estimates a release date of late-June 2018. The 5 mg/mL 30 mL vials are on back order and the company estimates a release date of mid-June 2018. The 7.5 mg/mL 20 mL Steripak ampules are on back order and the company estimates a release date of early- to mid-July 2018. The 10 mg/mL 20 mL vials are on back order and the company estimates a release date of early-July 2018. The 10 mg/mL 10 mL and 20 mL Steripak ampules are on back order and the company estimates a release date of mid-July 2018. Check wholesalers for inventory.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=384>

## Piperacillin and Tazobactam Injection

June 7, 2018

### Reason for the Shortage

- Apotex has piperacillin/tazobactam on shortage due to regulatory delays.
- AuroMedics and Sandoz could not provide a reason for the shortage.
- Fresenius Kabi has piperacillin/tazobactam on shortage due to increased demand.
- Mylan Institutional launched piperacillin/tazobactam 3.375 gram and 4.5 gram vials in early-June 2016.
- Pfizer has Zosyn single dose vials and piperacillin/tazobactam on shortage due to manufacturing delays.
- Sagent has piperacillin/tazobactam on shortage due to increased demand.
- Sandoz has piperacillin/tazobactam available for contracted customers.
- WG Critical Care states the reason for the shortage is increased demand.
- FDA in conjunction with SteriMax was allowing temporary importation of piperacillin/tazobactam 3.375 gram, 4.5 gram, and 40.5 gram vials from Canada. This was being distributed through X-Gen Pharmaceuticals. These are no longer being imported with the launch



of the products from X-Gen. The product codes on these items will not be recognized by U.S. systems so institutions will need to implement alternative plans to assure the dose is being given correctly. More information can be found on the FDA site at:  
<https://www.fda.gov/downloads/Drugs/DrugSafety/DrugShortages/UCM543149.pdf>.

- Wockhardt has piperacillin/tazobactam injection available.
- X-Gen has piperacillin/tazobactam injection available.

#### Estimated Resupply Dates

- Apotex has piperacillin/tazobactam 3.375 gram and 40.5 gram vials on back order and the company cannot estimate a release date.
- AuroMedics has piperacillin/tazobactam 2.25 gram, 3.375 gram, and 4.5 gram vials available.
- Baxter has Zosyn 2.25 gram/50 mL, 3.375 gram/50 mL, and 4.5 gram/50 mL premixed bags available in limited supply.
- Mylan has piperacillin/tazobactam 3.375 gram vials available with a short expiration date (expiration September 2018).
- Pfizer has Zosyn 2.25 gram vials, 3.375 gram vials, 4.5 gram vials, and 40.5 gram vials on back order and the company estimates a release date of 2019. Pfizer has piperacillin/tazobactam 3.375 gram and 4.5 gram ADD-Vantage vials available in limited supply.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=158>

#### Methocarbamol Tablets

**June 7, 2018**

#### Reason for the Shortage

- No supplier provided a reason for the shortage.

#### Estimated Resupply Dates

- Camber has all methocarbamol tablets on intermittent back order and the company estimates a release date of mid-June 2018.
- Par has methocarbamol 750 mg tablets in 100 count, 500 count, and 1000 count on back order and the company cannot estimate a release date.
- Solco has methocarbamol 500 mg tablets in 100 count and 500 count and 750 mg tablets in 100 count and 500 count on allocation.
- Virtus has methocarbamol 500 mg tablets in 100 count and 500 count and 750 mg tablets in 100 count and 500 count available.
- West-Ward has methocarbamol 750 mg tablets in 100 count and 500 count on back order and the company cannot estimate a release date. Methocarbamol 500 mg tablets in 100 count and 500 count are on allocation.
- Endo has Robaxin 500 mg and 750 mg tablets in 100 count on back order and the company estimates a release date of early-August 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=423>

#### Lactated Ringer's Injection

**June 7, 2018**

#### Reason for the Shortage

- Baxter did not provide a reason for the shortage.
- BBraun states the reason for the shortage is increased demand.



- ICU Medical states the reason for the shortage is increased demand.

#### Estimated Resupply Dates

- Baxter has lactated ringer's 250 mL bags on back order and the company could not estimate a release date. The 500 mL and 1000 mL bags are on allocation. Lactated ringer's with 5% dextrose 500 mL and 1000 mL bags are also on allocation.
- BBraun has lactated ringer's injection solution and lactated ringer's with 5% dextrose injection solution products on allocation to current customers.
- ICU Medical has lactated ringer's 500 mL bags on intermittent back order and the company is releasing supplies as they become available. Lactated ringer's with 5% dextrose 1000 mL bags are available in limited supply.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=361>

#### Fluorescein Sodium Ophthalmic Strips

**June 7, 2018**

#### Reason for the Shortage

- Hub did not provide a reason for the shortage.
- Akorn did not provide a reason for the shortage.

#### Estimated Resupply Dates

- Akorn has Ful-Glo 0.6 mg and 1 mg strips on back order and the company estimates a release date of 3rd quarter 2018 for the 0.6 mg strips and July 2018 for the 1 mg strips.
- Hub has Bio-Glo 1 mg strips on back order and the company estimates a release date of late-June 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=362>

#### Epinephrine Injection

**June 7, 2018**

#### Reason for the Shortage

- Amphastar stopped distributing epinephrine 1 mg/mL 30 mL vials on May 10, 2017. They are continuing to supply 0.1 mg/mL 10 mL syringes. These are on shortage due to increased demand.
- Pfizer stopped distributing epinephrine 1 mg/mL presentations on May 10, 2017.
- BPI has epinephrine 1 mg/mL 2 mL ampules available.
- Par has Adrenalin 1 mg/mL 1 mL and 30 mL vials available.

#### Estimated Resupply Dates

- Amphastar has epinephrine 0.1 mg/mL 10 mL syringes on allocation.
- Pfizer has epinephrine 0.1 mg/mL 10 mL syringes on back order and the company estimates a release date of June 2018.
- Snap Medical Industries has the Epinephrine Snap-V Kit available. Each kit contains an epinephrine 1 mg/mL 1 mL vial, (3) 1 mL luer lock syringes, and (3) 23-gauge 1-inch needles.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=313>

## Morphine Pca Vials

June 8, 2018

### Reason for the Shortage

- ICU Medical has morphine PCA vials on allocation due to increased demand.

### Estimated Resupply Dates

- ICU Medical has morphine PCA vials on allocation.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=436>

## Chlorothiazide Sodium Injection

June 8, 2018

### Reason for the Shortage

- Akorn has chlorothiazide injection on shortage due to manufacturing delays.
- Sagent had chlorothiazide injection on shortage due to increased demand.
- Sun Pharma refuses to provide availability information on any of their products.

### Estimated Resupply Dates

- American Regent has chlorothiazide 500 mg vials on back order and the company cannot estimate a release date.
- Mylan Institutional has chlorothiazide 500 mg vials available.
- Sun Pharma has chlorothiazide 500 mg vials on back order and the company cannot estimate a release date.
- Akorn has chlorothiazide 500 mg vials on back order and the company cannot estimate a release date.
- Akorn has Sodium Diuril 500 mg vials on back order and the company is allocating product upon release.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=365>

## Carbidopa and Levodopa Extended-Release Tablets

June 8, 2018

### Reason for the Shortage

- Accord has discontinued carbidopa and levodopa 25 mg/100 mg extended-release tablets. The 50 mg/200 mg tablets are on shortage due to problems obtaining active ingredient.
- Sun Pharma had carbidopa and levodopa extended-release tablets on shortage due to increased demand.
- Merck had Sinemet CR on shortage due to increased demand.
- Mylan could not provide a reason for the shortage.

### Estimated Resupply Dates

- Accord has carbidopa and levodopa 50 mg/200 mg extended-release tablets on allocation.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=349>

## Bupivacaine Injection

June 8, 2018

### Reason for the Shortage

- AuroMedics has not provided a reason for the shortage.
- Fresenius Kabi had Sensorcaine on shortage due to increased demand for the product.
- Pfizer has bupivacaine on shortage due to manufacturing delays. Pfizer discontinued 0.5% bupivacaine 30 mL glass ampules in December 2017.

### Estimated Resupply Dates

- AuroMedics has 0.25% bupivacaine 10 mL and 30 mL preservative-free vials on back order and the company cannot estimate a release date. The 0.5% bupivacaine 10 mL and 30 mL preservative-free vials are on back order and the company cannot estimate a release date. The 0.75% bupivacaine 10 mL and 30 mL preservative-free vials are on back order and the company cannot estimate a release date.
- Fresenius Kabi has 0.25% Sensorcaine 10 mL preservative-free vials on back order and the company estimates a release date of late-June 2018. The 0.25% 50 mL vials are on back order and the company estimates a release date of early-July 2018. The 0.5% Sensorcaine 10 mL and 50 mL preservative-free vials are on back order and the company estimates release dates of mid-June 2018. The 0.5% Sensorcaine 30 mL preservative-free vials are on back order and the company estimates a release date of late-June 2018. The 0.75% Sensorcaine 10 mL and 30 mL preservative-free vials are available. The 0.25% (NDCs 63323-0464-31 and 63323-0464-37) and 0.5% Sensorcaine 30 mL preservative-free vials in sterile packs are on back order and the company cannot estimate release dates.
- Pfizer has 0.25% bupivacaine 10 mL preservative-free vials on back order and the company estimates a release date of July 2018. The 0.25% bupivacaine 30 mL and 50 mL vials are on back order and the company estimates release dates of June 2018. The 0.5% bupivacaine 10 mL and 30 mL preservative-free vials are on back order and the company estimates a release date of June 2018 for the 10 mL vials and August 2018 for the 30 mL vials. The 0.5% bupivacaine 50 mL vials are on back order and the company estimates a release date of July 2018. The 0.75% bupivacaine 10 mL and 30 mL preservative-free vials are on back order and the company estimates a release date of August 2018 for the 10 mL vials and November 2018 for the 30 mL vials. The bupivacaine 0.75% in 8.25% dextrose 2 mL ampules are on back order and the company estimates a release date of September 2018.
- Pfizer has all Marcaine presentations on back order and the company estimates a release date of 2019 except for the bupivacaine 0.75% in 8.25% dextrose 2 mL ampules are on back order with an estimated release date of July 2018.
- Baxter has bupivacaine 0.75% in 8.25% dextrose 2 mL ampules on back order and the company cannot estimate a release date.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=172>

## Amino Acids in Dextrose

June 8, 2018

### Reason for the Shortage

- Baxter has all Clinimix presentations on allocation due to delays because of the hurricane in Puerto Rico.
- Baxter has reintroduced Clinimix into the distribution channel.

## Estimated Resupply Dates

- Baxter has Clinimix 4.25%/20% in 1000 mL and 2000 mL bags, 4.25%/25% in 1000 mL and 2000 mL, and 5%/25% in 2000 mL bags on back order and the company cannot estimate a release date. All other presentations are on allocation.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=355>

## Amino Acid Products with Electrolytes and Calcium

**June 8, 2018**

### Reason for the Shortage

- Baxter has all Clinimix E with electrolytes plus calcium presentations on allocation due to delays because of the hurricane in Puerto Rico.
- Baxter has reintroduced Clinimix into the distribution channel.
- To help alleviate the critical drug shortages resulting from the aftermath of Hurricane Maria, FDA has allowed Baxter to temporarily import the following amino acid products: Clinimix N9G15E, Clinimix N9G20E, and Clinimix N14G30E solutions for infusion. Additional information can be found in the Dear Healthcare Professional Letter.

<https://www.fda.gov/downloads/Drugs/DrugSafety/DrugShortages/UCM584414.pdf>

### Estimated Resupply Dates

- Baxter has all amino acid products with electrolytes plus calcium on allocation.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=354>

## Amino Acid Products

**June 8, 2018**

### Reason for the Shortage

- Baxter has reintroduced amino acids into the distribution channel.[1]
- Baxter has most amino acid products on allocation due to delays because of Hurricane Maria in Puerto Rico.
- BBraun has all amino acid on allocation due to increased demand.[2]
- Pfizer has Aminosyn on back order due to an ingredient shortage which has caused a supply disruption. Pfizer has obtained the ingredient, but does not yet have an estimated date as to when manufacturing will resume.[3]

### Estimated Resupply Dates

- Baxter has their amino acid products on allocation.[1]
- BBraun has their amino acid products on allocation.[2]
- ICU Medical has Aminosyn 3.5% 1000 mL bags, Aminosyn 8.5% 500 mL and 500 mL with electrolytes bags, Aminosyn 10% 500 mL and 1000 mL bags, Aminosyn II 8.5% 500 mL and 500 mL with electrolytes bags, and Aminosyn II 10% 500 mL and 1000 mL bags on back order and the company estimates a release date of 1st quarter 2019.[3]

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=297>

## Yellow Fever Vaccine

June 11, 2018

### Reason for the Shortage

- Sanofi Pasteur states the shortage is due to production delays. [1]
- There are no other suppliers of yellow fever vaccine.
- Additional information on the yellow fever shortage is available at <http://wwwnc.cdc.gov/travel/news-announcements/yellow-fever-vaccine-shortage-2015>.

### Estimated Resupply Dates

- Sanofi Pasteur has YF-Vax multi-dose vials and single dose vials on back order and the company estimates a release date in late-2018.[1]
- FDA accepted an investigational new drug application in October 2016. This is for the importation of another yellow fever vaccine from France. The trade name of the imported product is Stamaril. The product information can be found at [https://s3.amazonaws.com/filecache.drivetheweb.com/mr5str\\_sanofipasteur/202281/969800.pdf](https://s3.amazonaws.com/filecache.drivetheweb.com/mr5str_sanofipasteur/202281/969800.pdf). The initial rollout began in April 2017. More information can be found at [https://www.cdc.gov/mmwr/volumes/66/wr/mm6617e2.htm?s\\_cid=mm6617e2\\_w](https://www.cdc.gov/mmwr/volumes/66/wr/mm6617e2.htm?s_cid=mm6617e2_w) or at <https://www.vaccineshoppe.com/index.cfm?fa=anon.content&n=YellowFever&title=>.  
<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=197>

## Trace Elements Injection

June 11, 2018

### Reason for the Shortage

- American Regent is focusing on marketing Multitrace presentations.

### Estimated Resupply Dates

- All marketed presentations are available.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=319>

## Torsemid Injection

June 11, 2018

### Reason for the Shortage

- Roche discontinued Demadex injection for business reasons. Demadex tablets are not affected by this shortage.
- American Regent has tosemid on shortage due to manufacturing delays.

### Estimated Resupply Dates

- American Regent has tosemid injection on long-term back order and the company cannot estimate a release date.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=168>

## Sodium Phosphate Injection

June 11, 2018

### Reason for the Shortage

- American Regent has sodium phosphate injection on shortage due to manufacturing delay.[1]
- Fresenius Kabi states the reason for the shortage is increased demand.[2]
- Pfizer has sodium phosphate injection on shortage due to manufacturing delay.[3]

#### Estimated Resupply Dates

- American Regent has sodium phosphate 3 mmol/mL 5 mL, 15 mL, and 50 mL vials on back order and the company cannot estimate a release date.[1]
- Fresenius Kabi has all sodium phosphate presentations available.[2]
- Pfizer has sodium phosphate 3 mmol/mL 15 mL vials on back order and the company estimates a release date of 2019.[3]

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=227>

### Remifentanil Injection

**June 11, 2018**

#### Reason for the Shortage

- Mylan Institutional did not provide a reason for the shortage.
- Fresenius Kabi launched generic remifentanil in January 2018.

#### Estimated Resupply Dates

- Mylan Institutional has Ultiva 2 mg and 5 mg vials on back order and the company estimates a release date of mid- to late-June 2018 for the 2 mg vials and mid-June 2018 for the 5 mg vials.
- Fresenius Kabi has remifentanil 1 mg, 2 mg, and 5 mg vials on back order and the company estimates a release date of late-July 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=371>

### Morphine Injection

**June 11, 2018**

#### Reason for the Shortage

- Fresenius Kabi procured morphine syringes from BD in 2016. They discontinued the 8 mg/mL and 10 mg/mL 1 mL syringes in early-2018.[1-2]
- Astramorph injection has been unavailable since 2012. Fresenius Kabi changed manufacturing sites and cannot estimate if Astramorph will return.[2]
- Pfizer states the shortage is due to manufacturing delays. Pfizer discontinued morphine ADD-Vantage vials in January 2017.[3]
- Pfizer anticipates a shortage of several prefilled syringe products, including morphine, starting in late-July 2017 due to issues at a manufacturing facility. To minimize the impact of the shortage, Pfizer is prioritizing production of certain morphine Carpuject syringes. Pfizer expects the shortage of prefilled syringe products to recover by late-first quarter 2018.[3]
- West-Ward did not provide a reason for the shortage. West-Ward is not actively marketing the 15 mg/mL 1 mL vials or the 8 mg/mL 1 mL vials (NDC 00641-6075-25). They are still marketing the 8 mg/mL 1 mL vials with NDC 00641-6126-25.[4]

#### Estimated Resupply Dates

- Fresenius Kabi has morphine 2 mg/mL 1 mL syringes on back order and the company estimates a release date of mid- to late-June 2018. The morphine 4 mg/mL 1 mL syringes are on back order and the company estimates a release date of early- to mid-June 2018. The morphine 5 mg/mL 1



mL syringes are on back order and the company cannot estimate a release date. Check wholesalers for inventory. New morphine sulfate vial presentations are available.[2]

- Pfizer has morphine 2 mg/mL 1 mL Carpuject syringes on back order and the company estimates a release date of June 2018. The 4 mg/mL 1 mL Carpuject syringes are on back order and the company cannot estimate a release date. The 0.5 mg/mL preservative-free vials are available in limited supply. The 1 mg/mL 10 mL preservative-free vials are on back order and the company estimates a release date of mid-June 2018. The 2 mg/mL 1 mL iSecure syringes, 4 mg/mL 1 mL iSecure syringes, 8 mg/mL 1 mL Carpuject syringes, 8 mg/mL 1 mL iSecure syringes, 10 mg/mL 1 mL iSecure syringes, and 10 mg/mL 1 mL Carpuject syringes are on back order and the company estimates a release date of June 2019. The 25 mg/mL 1 mL preservative-free vials are on back order and the company estimates a release date of June 2018. The 50 mg/mL 50 mL vials are on back order and the company estimates a release date of June 2018. The 50 mg/mL 20 mL vials are available in limited supply.[3]
- West-Ward has morphine 4 mg/mL 1 mL vials and 10 mg/mL 1 mL vials are on allocation. The 8 mg/mL 1 mL vials are on back order and the company cannot estimate a release date. Infumorph 10 mg/mL 20 mL ampules and 25 mg/mL 20 mL ampules are on back order and the company cannot estimate a release date. Duramorph 1 mg/mL 10 mL ampules are on allocation. Duramorph 0.5 mg/mL 10 mL ampules are on back order and the company estimates a release date of mid- to late-June 2018.[4]

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=41>

## Magnesium Sulfate Injection

June 11, 2018

### Reason for the Shortage

- American Regent has had magnesium sulfate unavailable since late 2012.
- Fresenius Kabi has magnesium sulfate injection on shortage due to increased demand for the product.
- Pfizer has magnesium sulfate injection on shortage due to manufacturing delays.
- X-Gen discontinued magnesium sulfate in April 2018.
- Exela launched magnesium sulfate vials in May 2108.

### Estimated Resupply Dates

- Fresenius Kabi has magnesium sulfate 500 mg/mL 2 mL, 10 mL, 20 mL and 50 mL vials on back order and the company estimates a release date of early-July 2018 for the 2 mL vials, late-July 2018 for the 10 mL vials, mid- late-June for the 20 mL vials, and late-June 2018 for the 50 mL vials. The 40 mg/mL 100 mL and 500 mL premixed bags are on back order and the company estimates a release date of mid-July 2018 for the 100 mL bags and late-July 2018 for the 500 mL bags. The 40 mg/mL 50 mL premixed bags are on back order and the company estimates a release date of mid-June 2018. The 80 mg/mL 50 mL premixed bags are on back order and the company estimates a release date of early- to mid-July 2018.
- Pfizer has magnesium sulfate 500 mg/mL 20 mL vials on back order and the company estimates a release date of 2019. The 500 mg/mL 10 mL syringes are on back order and the company estimates a release date of September 2018. The magnesium sulfate 10 mg/mL 100 mL bags are available in limited supply. The magnesium sulfate 40 mg/mL 50 mL and 100 mL bags are on back order and the company estimates a release date of August 2018. The 40 mg/mL 500 mL bags are available in limited supply. The 80 mg/mL 50 mL bags are available in limited supply.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=21>

## Lidocaine Injection

June 11, 2018

### Reason for the Shortage

- Amphastar had lidocaine 2% emergency syringes on shortage due to increase demand for the product.
- AuroMedics introduced lidocaine injection in February 2014.
- Fresenius Kabi had generic lidocaine presentations on shortage due to a supply interruption of raw ingredients.
- Pfizer has lidocaine presentations on shortage due to manufacturing delays.

### Estimated Resupply Dates

- AuroMedics has 1% lidocaine 5 mL ampules and 2 mL, 5 mL, and 30 mL vials on intermittent back order and the company is releasing product as it becomes available. AuroMedics has 2% lidocaine 2 mL ampules and 5 mL vials on intermittent back order and the company is releasing product as it becomes available.
- Fresenius Kabi has 0.5% Xylocaine 50 mL vials on back order and the company estimates a release date of late-July to early-August 2018. The 1% lidocaine 2 mL and 10 mL vials are on back order and the company estimates a release date of early-July 2018 for the 2 mL vials and mid-June 2018 for the 10 mL vials. The 1% Xylocaine 20 mL and 50 mL vials are on back order and the company estimates a release date of early-July 2018. The 1% Xylocaine-MPF 2 mL and 5 mL vials are on back order and the company estimates a release date of mid-June 2018. The 1% Xylocaine-MPF 30 mL vials are on back order and the company estimates a release date of early-July 2018. The 1% Xylocaine-MPF 30 mL vial sterile packs are on back order and the company cannot estimate a release date. The 2% Xylocaine-MPF 2 mL and 5 mL vials are on back order and the company estimates a release date of mid-June 2018. The 2% Xylocaine 10 mL, 20 mL, and 50 mL vials are on back order and the company estimates a release date of early-July 2018 for the 10 mL vials, mid- to late-June 2018 for the 20 mL vials, and late-June 2018 for the 50 mL vials. The 2% lidocaine 2mL vials and 5 mL preservative free vials are on back order and the company estimates a release date of late-June 2018 for the 2 mL vials and mid-June 2018 for the 5 mL vials. Check wholesalers for inventory.
- Pfizer has 1% lidocaine 2 mL preservative-free ampules on back order and the company estimates a release date of July 2018. The 1% lidocaine 5 mL preservative-free ampules are on back order and the company estimates a release date of 2019. The 1% lidocaine 20 mL vials are on back order and the company estimates a release date of July 2018. The 1% lidocaine 30 mL preservative-free vials are on back order and the company estimates a release date of June 2018. The 1% lidocaine 50 mL vials are on back order and the company estimates a release date of September 2018. The 1% lidocaine 5 ml LifeShield syringes are on back order and the company estimates a release date of June 2018. The 2% lidocaine 2 mL preservative-free ampules are on back order and the company estimates a release date of September 2018. The 2% lidocaine 5 mL vials are on back order and the company estimates a release date of 2019. The 2% lidocaine 20 mL and 50 mL vials are on back order and the company estimates a release date of August 2018. The 2% lidocaine 5 mL Lifeshield syringes are on back order and the company estimates a release date in June 2018. The 4% lidocaine 5 mL ampules are on back order and the company estimates a release date of August 2018.
- West-Ward has 1% lidocaine 5 mL preservative-free vials, 1% lidocaine 50 mL vials, and 2% lidocaine 50 mL vials on allocation. The 2% lidocaine 5 mL preservative free vials are on back order and the company estimates a release date of July to August 2018.



<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=88>

### Lidocaine Hydrochloride and 5% Dextrose Injection

**June 11, 2018**

#### Reason for the Shortage

- Baxter did not provide a reason for the shortage.
- BBraun did not provide a reason for the shortage.

#### Estimated Resupply Dates

- Baxter has lidocaine and 5% dextrose 4 mg/mL 500 mL and 8 mg/mL 250 mL premixed bags on allocation.
- BBraun has lidocaine and 5% dextrose 4 mg/mL 250 mL, 4 mg/mL 500 mL, and 8 mg/mL 250 mL premixed bags on allocation to contracted customers.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=372>

### Leucovorin Calcium Injection

**June 11, 2018**

#### Reason for the Shortage

- Fresenius Kabi did not provide a reason for the current shortage.
- Sagent has leucovorin on shortage due to manufacturing delays.
- Teva has leucovorin available.
- West-Ward did not provide a reason for the current shortage.

#### Estimated Resupply Dates

- Fresenius Kabi has leucovorin 200 mg vials on back order and the company expects a release date of early-July 2018.
- Sagent has leucovorin 350 mg vials on allocation.
- West-Ward has leucovorin 100 mg, 200 mg, and 350 mg vials on allocation. The 50 mg vials are on back order and the company estimates a release date of late-June to early-July 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=35>

### Ketamine Injection

**June 11, 2018**

#### Reason for the Shortage

- Mylan Institutional did not provide a reason for the shortage.
- Par has Ketalar on shortage due to increased demand.
- Pfizer has ketamine on shortage due to manufacturing delays.
- West-Ward did not provide a reason for the shortage.

#### Estimated Resupply Dates

- Mylan Institutional has ketamine 10 mg/mL 20 mL vials on back order and the company estimates a release date of mid-June 2018.
- Pfizer has ketamine 50 mg/mL 10 mL vials and 100 mg/mL 5 mL vials on back order and the company estimates a release date of 2019.
- West-Ward has ketamine 50 mg/mL 10 mL vials and 100 mg/mL 5 mL vials on allocation.

- Par has Ketalar 10 mg/mL 20 mL vials, 50 mg/mL 10 mL vials, and 100 mg/mL 5 mL vials on intermittent back order with regular releases.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=391>

## Hypromellose Ophthalmic Solution

**June 11, 2018**

### Reason for the Shortage

- Akorn has hypromellose ophthalmic solution on shortage due to lack of raw materials.
- HUB Pharmaceuticals has hypromellose ophthalmic solution on long-term back order and did not provide a reason.

### Estimated Resupply Dates

- Akorn has hypromellose 2.5% ophthalmic solution 15 mL bottles on back order and the company estimates a release date of August 2018.
- HUB Pharmaceuticals has hypromellose 2.5% ophthalmic solution 15 mL bottles on long-term back order and the company cannot estimate a release date.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=437>

## Eflornithine Hydrochloride Cream

**June 11, 2018**

### Reason for the Shortage

- Allergan did not provide a reason for the shortage.

### Estimated Resupply Dates

- Allergan has Vaniqa cream on back order and the company estimates a release date in December 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=438>

## Doxorubicin Injection

**June 11, 2018**

### Reason for the Shortage

- West-Ward has Adriamycin available.
- Teva has doxorubicin solution for injection on shortage due to increased demand.
- Fresenius Kabi has doxorubicin solution for injection available.
- Caraco has discontinued doxorubicin solution for injection 25 mL and 100 mL vials.
- Pfizer has doxorubicin on shortage due to manufacturing delays.
- Sagent discontinued doxorubicin solution for injection in late-2017.
- Mylan Institutional has doxorubicin lyophilized powder for injection available.
- Athenex has doxorubicin available.
- FDA was allowing temporary importation of doxorubicin lyophilized powder for injection 50 mg vials. These vials were manufactured for Hospira UK Limited. The labeling as well as bar coding for the imported product is different from the US version. FDA has the Dear Healthcare Professional Letter linked on their website. The letter includes a link to both the US and United Kingdom package inserts to help explain the differences in labeling and packaging. The link to

the letter is <http://www.fda.gov/downloads/Drugs/DrugSafety/DrugShortages/UCM507498.pdf>.  
Ordering can be done directly with Hospira Customer Care at 877-946-7747.

#### Estimated Resupply Dates

- Mylan Institutional has doxorubicin lyophilized powder 10 mg vials on back order and the company cannot estimate a release date. The 50 mg vials are available with an expiration date of January 2019.
- Teva has doxorubicin 2 mg/mL 100 mL vials (NDC 45963-0733-60) on back order and the company will allocate these as they become available.
- West-Ward has Adriamycin 2 mg/mL 5 mL vials available with short expiration dating (expiry July 2018).

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=108>

## Bupivacaine with Epinephrine Injection

June 11, 2018

#### Reason for the Shortage

- Fresenius Kabi has bupivacaine and epinephrine on shortage due to increased demand and manufacturing delays.
- Pfizer has bupivacaine with epinephrine on shortage due to manufacturing delays.

#### Estimated Resupply Dates

- Fresenius Kabi has 0.25% Sensorcaine-MPF with epinephrine 10 mL vials on back order and the company cannot estimate a release date. The 0.25% Sensorcaine-MPF with epinephrine 30 mL vials are on back order and the company estimates a release date of mid- to late-June 2018. The 0.25% Sensorcaine with epinephrine 50 mL vials are on back order and the company estimates a release date of late-June 2018. The 0.5% Sensorcaine-MPF with epinephrine 10 mL vials are on back order and the company cannot estimate a release date. The 0.5% Sensorcaine-MPF with epinephrine 30 mL vials are on back order and the company estimates a release date of mid-June 2018. The 0.5% Sensorcaine-MPF with epinephrine 30 mL sterile packs are on back order and the company cannot estimate a release date. The 0.5% Sensorcaine with epinephrine 50 mL vials are on back order and the company estimates a release date of mid- to late-June 2018. The 0.75% Sensorcaine with epinephrine 30 mL vials are on back order and the company cannot estimate a release date.
- Pfizer has 0.25% bupivacaine with epinephrine 10 mL preservative-free vials on back order and the company estimates a release date of June 2018. The 0.25% bupivacaine with epinephrine 30 mL preservative-free vials are on back order and the company estimates a release date of July 2018. The 0.25% bupivacaine with epinephrine 50 mL vials are on back order and the company estimates a release date of August 2018. The 0.5% bupivacaine with epinephrine 10 mL preservative-free vials are on back order and the company estimates a release date of 2019. The 0.5% bupivacaine with epinephrine 30 mL preservative-free vials are on back order and the company estimates a release date of July 2018. The 0.5% bupivacaine with epinephrine 50 mL vials are on back order and the company estimates a release date of August 2018.
- Pfizer has 0.25% Marcaine with epinephrine 10 mL and 30 mL preservative-free vials on back order and the company estimates a release date of 2019. The 0.25% Marcaine with epinephrine 50 mL vials are on back order and the company estimates a release date of 2019. The 0.5% Marcaine with epinephrine 10 mL and 30 mL preservative-free vials are on back order and the

company estimates a release date of 2019. The 0.5% Marcaine with epinephrine 50 mL vials are on back order and the company estimates a release date of 2019.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=261>

## Azithromycin Injection

**June 11, 2018**

### Reason for the Shortage

- Pfizer has azithromycin injection on shortage due to manufacturing delays.
- AuroMedics did not provide a reason for the shortage.
- Sun Pharma did not provide a reason for the shortage.

### Estimated Resupply Dates

- AuroMedics has azithromycin 500 mg vials on intermittent back order and the company is releasing product as it becomes available.
- Pfizer has azithromycin 500 mg ADD-Vantage vials on back order and the company estimates a release date of 2019.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=380>

## 50% Dextrose Injection

**June 11, 2018**

### Reason for the Shortage

- Amphastar has 50% dextrose injection available.
- Pfizer has 50% dextrose injection on shortage due to manufacturing delays.

### Estimated Resupply Dates

- Pfizer has 50% dextrose 50 mL LifeShield syringes on back order and the company estimates a release date in July 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=306>

## 3% and 5% Sodium Chloride Large Volume Injection

**June 11, 2018**

### Reason for the Shortage

- Baxter has 3% and 5% sodium chloride large volume for injection available.
- BBraun did not provide a reason for the shortage.

### Estimated Resupply Dates

- BBraun has 3% sodium chloride 500 mL bags and 5% sodium chloride 500 mL bags on allocation to current customers.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=415>

## 23.4% Sodium Chloride Injection

**June 11, 2018**

### Reason for the Shortage

- Fresenius Kabi has 23.4% sodium chloride injection on shortage due to increased demand.

- Pfizer has 23.4% sodium chloride injection on shortage due to increased demand.

#### Estimated Resupply Dates

- Fresenius Kabi has 23.4% sodium chloride 30 mL, 100 mL, and 200 mL vials on back order and the company estimates a release date of early- to mid-June 2018 for the 30 mL vials, late-June 2018 for the 100 mL vials, and cannot estimate a release date for the 200 mL vials. Check wholesalers for inventory.
- Pfizer has 23.4% sodium chloride 200 mL vials on back order and the company estimates a release date of June 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=336>

#### Hydralazine Injection

**June 12, 2018**

#### Reason for the Shortage

- Akorn has product on back order due to increased demand.
- American Regent did not provide a reason for the shortage.
- Fresenius Kabi did not provide a reason for the shortage.
- X-Gen did not provide a reason for the shortage.

#### Estimated Resupply Dates

- Akorn has hydralazine 20 mg/mL 1 mL vials on back order and the company cannot estimate a release date.
- American Regent has hydralazine 20 mg/mL 1 mL vials on back order and the company cannot estimate a release date.
- Fresenius Kabi has hydralazine 20 mg/mL 1 mL vials on back order and the company estimates a release date of mid-June 2018.
- X-Gen has hydralazine 20 mg/mL 1 mL vials on back order and the company estimates a release date of mid-June 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=431>

#### Atropine Sulfate Injection

**June 12, 2018**

#### Reason for the Shortage

- American Regent had atropine injection on shortage due to market demand.
- Amphastar has atropine injection available.
- Pfizer has atropine injection on shortage due to manufacturing delays.
- West-Ward has atropine injection available.

#### Estimated Resupply Dates

- Pfizer has atropine 0.1 mg/mL 10 mL Ansyr syringes, 0.1 mg/mL 5 mL LifeShield syringes, and 0.1 mg/mL 10 mL LifeShield syringes on back order and the company estimates release dates of July 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=46>

## Atropine Ophthalmic Solution

June 12, 2018

### Reason for the Shortage

- Akorn did not provide a reason for the shortage.

### Estimated Resupply Dates

- Akorn has atropine ophthalmic solution in 5 and 15 mL bottles available, but short-dated. The 2 mL bottles are on back order and the company cannot estimate a release date.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=429>

## Vecuronium Bromide Injection

June 13, 2018

### Reason for the Shortage

- Pfizer has vecuronium on shortage due to manufacturing delays.
- Teva had vecuronium on allocation due to increased demand.
- Pfizer sold vecuronium injection to Mylan Institutional in December 2013.
- Ben Venue has stopped production in its plant in Bedford, Ohio and closed in 2014.
- Sun Pharma has vecuronium available.
- Sagent is not marketing vecuronium 10 mg and 20 mg vials.
- Fresenius Kabi had vecuronium on shortage due to manufacturing delays.

### Estimated Resupply Dates

- Mylan Institutional has vecuronium 20 mg vials on back order with an estimated release date of January 2019.
- Pfizer has vecuronium 10 mg and 20 mg vials on back order and the company estimates a release date of 2019.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=167>

## Midodrine Tablets

June 13, 2018

### Reason for the Shortage

- Avkare did not provide a reason for the shortage.
- Upsher-Smith did not provide a reason for the shortage.

### Estimated Resupply Dates

- Avkare has midodrine 2.5 mg, 5 mg, and 10 mg tablets in 90-count bottles on back order and the company cannot estimate a release date.
- Upsher-Smith has midodrine 5 mg and 10 mg tablets in 100-count bottles on back order and the company estimates a release date of mid-June 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=439>

## Lidocaine with Epinephrine Injection

June 13, 2018

### Reason for the Shortage

- Fresenius Kabi has Xylocaine with epinephrine presentations on shortage due to increased demand for the product and manufacturing delays.
- Pfizer has lidocaine with epinephrine presentations on shortage due to manufacturing delays.

## Estimated Resupply Dates

- Pfizer has 0.5% lidocaine with epinephrine (1:200,000) 50 mL vials on back order and the company estimates a release date of July 2018. The 1% lidocaine with epinephrine (1:100,000) 20 mL and 50 mL vials are on back order and the company estimates a release date of July 2018. The 1% lidocaine with epinephrine (1:100,000) 30 mL vials are on back order and the company estimates a release date of June 2018. The 1.5% lidocaine with epinephrine (1:200,000) 30 mL vials are on back order and the company estimates a release date of October 2018. The 2% lidocaine with epinephrine (1:100,000) 20 mL and 50 mL vials are on back order and the company estimates a release date of July 2018.
- Fresenius Kabi has 0.5% Xylocaine with epinephrine (1:200,000) 50 mL vials on back order and the company cannot estimate a release date. The 1% Xylocaine with epinephrine (1:200,000) 10 mL vials are on back order and the company cannot estimate a release date. The 1% Xylocaine with epinephrine (1:200,000) 20 mL and 50 mL vials are on back order and the company estimates release dates of mid- to late-June 2018 for the 20 mL vials and mid-June 2018 for the 50 mL vials. The 1% Xylocaine-MPF with epinephrine (1:200,000) 10 mL vials are on back order and the company cannot estimate a release date. The 1% Xylocaine-MPF with epinephrine (1:200,000) 30 mL vials are on back order and the company estimates a release date of mid-June 2018. The 1% Xylocaine-MPF with epinephrine (1:200,000) 30 mL vials in sterile packs are on back order and the company cannot estimate a release date. The 1.5% Xylocaine-MPF with epinephrine (1:200,000) 30 mL vials in sterile packs are on back order and the company cannot estimate a release date. The 1.5% Xylocaine-MPF with epinephrine (1:200,000) 10 mL regular vials and 30 mL vials are on back order and the company cannot estimate a release date. The 2% Xylocaine with epinephrine (1:200,000) 20 mL and 50 mL vials are on back order and the company and the company estimates a release date of early-July 2018. The 2% Xylocaine-MPF with epinephrine (1:200,000) 10 mL vials and 20 mL vials in sterile packs are on back order and the company cannot estimate a release date. Check wholesalers for inventory.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=98>

## Hydromorphone Hydrochloride Injection

**June 13, 2018**

### Reason for the Shortage

- Akorn has hydromorphone injection on shortage due to increased demand.[1]
- Fresenius Kabi has Dilaudid syringes on shortage due to increased demand. They are focusing their product on the 0.5 mg strength.[2]
- Pfizer did not provide a reason for the shortage.[3]
- Purdue discontinued Dilaudid and Dilaudid HP in May 2017 for marketing reasons.[4]
- Teva did not provide a reason for the shortage.[5]
- West-Ward did not provide a reason for the shortage.[6]

### Estimated Resupply Dates

- Akorn has hydromorphone 10 mg/mL 1 mL ampules, 5 mL ampules, and 50 mL vials on intermittent back order and the company is allocating product upon release.[1]



- Fresenius Kabi has Dilaudid 0.5 mg/mL 0.5 mL and 1 mg/mL 1 mL syringes on back order and the company estimates a release date of late-June 2018 for the 0.5 mL syringes and late-July 2018 for the 1 mL syringes. The 2 mg/mL 1 mL syringes are on back order and the company cannot estimate a release date.[2]
  - Pfizer has 2 mg/mL 1 mL vials, 10 mg/mL 1 mL vials, and 10 mg/mL 50 mL vials on back order and the company estimates a release date of late-June 2018. The 10 mg/mL 5 mL vials are on back order and the company estimates a release date of mid-July 2018. The 1 mg/mL 1 mL and 2mg/mL 1 mL Carpuject syringes are on back order and the company estimates a release date of June 2018. The 0.5 mg/0.5 mL 0.5 mL iSecure syringes are on back order and the company estimates a release date in July 2018. The 1 mg/mL 1 mL ampules, 2 mg/mL 1 mL ampules, and 4 mg/mL 1 mL ampules are on back order and the company cannot estimate a release date. The 1 mg/mL 1 mL iSecure syringes, 2 mg/mL 1 mL iSecure syringes, and 4 mg/mL 1 mL Carpuject syringes are on back order and the company estimates a release date of June 2019.[3]
  - Teva has hydromorphone 10 mg/mL 1 mL, 5 mL, and 50 mL vials on intermittent back order and the company is allocating product upon release.[5]
  - West-Ward has hydromorphone 2 mg/mL 1 mL and 20 mL vials on allocation.[6]
- <https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=329>

## Furosemide Tablets

**June 13, 2018**

### Reason for the Shortage

- Major discontinued furosemide tablets in early-2018.
- Mylan and Teva did not provide a reason for the shortage.
- West-Ward states the shortage is due to manufacturing delays.
- Sandoz discontinued furosemide tablets in late-August 2017.
- Teva discontinued furosemide tablets in June 2018

### Estimated Resupply Dates

- Mylan has furosemide 40 mg tablets in 100 count and 1000 count on back order and the company estimates a release date of late-August 2018.
- West-Ward has furosemide 20 mg tablets in 100 count and 1000 count bottles on allocation. The 40 mg tablets in 100 count and 1000 count bottles are on allocation.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=339>

## Dexmedetomidine Hydrochloride Injection

**June 13, 2018**

### Reason for the Shortage

- Akorn did not provide a reason for the shortage.
- Athenex has dexmedetomidine vials available.
- Fresenius Kabi has dexmedetomidine vials available.
- Mylan has dexmedetomidine vials available.
- Pfizer did not provide a reason for the shortage.
- Sandoz has dexmedetomidine vials available.
- Teva has dexmedetomidine vials available.
- West-Ward has dexmedetomidine vials available.



## Estimated Resupply Dates

- Akorn has dexmedetomidine 100 mcg/mL 2 mL vials on back order and the company estimates a release date in mid-June 2018.
- Par has dexmedetomidine 100 mcg/mL 2 mL vials on back order and the company estimates a release date in mid-June 2018.
- Pfizer has Precedex 4 mcg/mL 50 mL and 100 mL premixed bottles on back order and the company estimates a release date in June 2018. The 4 mcg/mL 20 mL vials are on back order and the company estimates a release date in July 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=398>

## Cefoxitin Sodium Injection

**June 13, 2018**

### Reason for the Shortage

- Fresenius Kabi and West-Ward did not provide a reason for the shortage.
- Sagent had cefoxitin on shortage due to manufacturing delays.
- BBraun has cefoxitin on allocation due to increased demand.
- WG Critical Care did not provide a reason for the back order.
- Apotex did not provide a reason for the shortage.

### Estimated Resupply Dates

- Apotex has temporarily discontinued cefoxitin 1 gram, 2 gram, and 10 gram vials and the company cannot estimate when product will be available again.
- BBraun has cefoxitin 1 gram and 2 gram vials on allocation.
- Sagent has cefoxitin 1 gram vials on allocation.
- West-Ward has cefoxitin 1 gram, 2 gram, and 10 gram vials on back order and the company estimates a release date of late-June to early-July 2018 for the 1 gram vials and cannot estimate a release date for the 2 gram and 10 gram vials.
- WG Critical Care has cefoxitin 1 gram and 2 gram vials on back order and the company estimates a release date of late-June 2018 for the 1 gram vials and mid- to late-June 2018 for the 2 gram vials.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=271>

## Fluconazole Injection

**June 14, 2018**

### Reason for the Shortage

- Baxter, Renaissance Lakewood Pharmaceuticals, and West-Ward did not provide a reason for the fluconazole injection shortage.
- Pfizer has fluconazole injection on shortage due to manufacturing delays.
- Renaissance Lakewood Pharmaceuticals bought fluconazole in sodium chloride premixed bags from Claris Lifescience.
- Sagent has new NDC numbers for fluconazole in sodium chloride premixed bags.

### Estimated Resupply Dates

- Baxter has 200 mg/100 mL and 400 mg/200 mL in 0.9% sodium chloride premixed bags on allocation.

- Renaissance Lakewood has fluconazole injection 100 mg/50 mL in 0.9% sodium chloride in 10 count, 200 mg/100 mL in 0.9% sodium chloride in 6 count and 10 count, and 400 mg/200 mL in 0.9% sodium chloride in 10 count on back order and the company cannot estimate a release date. The fluconazole 400 mg/200 mL in 0.9% sodium chloride in 6 count are available in limited supply.
- West-Ward has all fluconazole injection presentations on back order. The company cannot estimate a release date for any of the presentations except for the 200 mg/100 mL in 5% dextrose premixed bags, which have an estimated release date of July to August 2018.
- Sagent has new NDC numbers for fluconazole injection in sodium chloride. Fluconazole 400 mg/200 mL in 0.9% sodium chloride is available under the new NDC. The old NDC has been discontinued. Fluconazole 200 mg/100 mL in 0.9% sodium chloride is on back order and the company has an estimated release date of July 2018. The new NDC for fluconazole 200 mg/100 mL in 0.9% sodium chloride has an estimated release date of September 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=318>

## Etoposide Solution for Injection

**June 15, 2018**

### Reason for the Shortage

- Accord has etoposide 20 mg/mL 5 mL and 25 mL vials on allocation and 50 mL vials on back order due to increased demand.
- Fresenius Kabi has etoposide on back order due to increased demand.
- Teva has Toposar on allocation due to increased demand.
- West-Ward did not provide a reason for the shortage.
- Etoposide phosphate powder for injection (Etopophos) is unaffected by this shortage.

### Estimated Resupply Dates

- Accord has etoposide 20 mg/mL 50 mL vials on back order and the company estimates a release date of July 2018.
- Fresenius Kabi has etoposide 20 mg/mL 5 mL and 25 mL vials on back order and the company estimates a release date of mid-June 2018 for the 5 mL vials and late-June 2018 for the 25 mL vials. Check wholesalers for inventory.
- Teva has Toposar 20 mg/mL 5 mL, 25 mL, and 50 mL vials on allocation.
- West-Ward has etoposide 20 mg/mL 5 mL and 25 mL vials on back order and the company estimates release dates of early- to mid-July 2018. The 50 mL vials are on allocation.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=369>

## 5% Dextrose Injection

**June 15, 2018**

### Reason for the Shortage

- Baxter did not provide a reason for the shortage.
- ICU Medical states the shortage is due to increased demand.
- Pfizer states that the shortage is due to increased demand.
- ICU Medical is now the IV fluid business of Pfizer after the acquisition of Hospira. Pfizer continues to market the ADD-vantage product.

### Estimated Resupply Dates

- Baxter has 5% dextrose 250 mL, 500 mL, and 1,000 mL bags on allocation.
- ICU Medical has 5% dextrose 500 mL (NDC 00409-7922-03) bags on back order and the company estimates a release date of late-June 2018. The 250 mL 2 port bags (NDC 00409-7922-02) are on back order and the company estimates a release date of late-June 2018.
- Pfizer has 5% dextrose 250 mL ADD-Vantage bags on back order with an estimated release date of July 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=303>

\*Please refer to ASHP website for more information at:  
<http://www.ashp.org/menu/DrugShortages/CurrentShortages/>