



Drug Information Update

March 2018

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NEWLY AVAILABLE GENERICS

GENERIC DRUG NAME	STRENGTH & DOSAGE FORM	GENERIC MANUFACTURER	BRAND NAME
MEMANTINE HCL ER	7MG CAPSULE	MYLAN	NAMENDA XR
MEMANTINE HCL ER	7MG CAPSULE	PAR PHARM.	NAMENDA XR
MEMANTINE HCL ER	7MG CAPSULE	AMNEAL PHARMACE	NAMENDA XR
MEMANTINE HCL ER	7MG CAPSULE	LUPIN PHARMACEU	NAMENDA XR
MEMANTINE HCL ER	14MG CAPSULE	MYLAN	NAMENDA XR
MEMANTINE HCL ER	14MG CAPSULE	PAR PHARM.	NAMENDA XR
MEMANTINE HCL ER	21MG CAPSULE	MYLAN	NAMENDA XR
MEMANTINE HCL ER	21MG CAPSULE	PAR PHARM.	NAMENDA XR
MEMANTINE HCL ER	21MG CAPSULE	AMNEAL PHARMACE	NAMENDA XR
MEMANTINE HCL ER	21MG CAPSULE	LUPIN PHARMACEU	NAMENDA XR
MEMANTINE HCL ER	28MG CAPSULE	MYLAN	NAMENDA XR
MEMANTINE HCL ER	28MG CAPSULE	PAR PHARM.	NAMENDA XR
MINOCYCLINE HCL ER	65MG TABLET	TEVA USA	SOLODYN
MINOCYCLINE HCL ER	65MG TABLET	IMPAX GENERICS	SOLODYN
MINOCYCLINE HCL ER	115MG TABLET	TEVA USA	SOLODYN
MINOCYCLINE HCL ER	115MG TABLET	IMPAX GENERICS	SOLODYN
SUMATRIPTAN SUCC-NAPROXEN	85MG-500MG	MACOVEN PHARMAC	TREXIMET
SUMATRIPTAN SUCC-NAPROXEN	85MG-500MG	AUROBINDO PHARM	TREXIMET
METHYLPHENIDATE HCL	10MG TABLET	MAYNE PHARMA IN	RITALIN LA
LANSOPRAZOLE	15MG CAPSULE	TEVA USA	PREVACID
LANSOPRAZOLE	30MG CAPSULE	TEVA USA	PREVACID
DROSPIR/ETH ESTRA/LEVOMEFOL CA	3mg-0.03MG (21 TABLETS)	BAYER, PHARM DIV	SAFYRAL
TIAGABINE HCL	12MG TABLET	TEVA USA	GABITRIL
TIAGABINE HCL	12MG TABLET	AMNEAL PHARMACE	GABITRIL
TIAGABINE HCL	16MG TABLET	TEVA USA	GABITRIL
TIAGABINE HCL	16MG TABLET	AMNEAL PHARMACE	GABITRIL
RITONAVIR	100MG TABLET	WEST-WARD, INC	NORVIR

NEW DRUG ENTITIES/COMBINATIONS/STRENGTHS

DESCRIPTION	BRAND NAME	GENERIC NAME	STRENGTH	NOTES
ANTICHOLINERGICS, ORALLY INHALED LONG ACTING	LONHALA MAGNAIR STARTER	GLYCOPYRROL/NEBULIZER/ACCESSOR	25 MCG/ML	New Entity
ANTICHOLINERGICS, ORALLY INHALED LONG ACTING	LONHALA MAGNAIR REFILL	GLYCOPYRROLATE/NEB.ACCESSORIES	25 MCG/ML	New Entity
PANCREATIC ENZYMES	ZENPEP	LIPASE/PROTEASE/AMYLASE	5,000 UNIT-17,000 UNIT-24,000 UNIT	New Strength
PANCREATIC ENZYMES	ZENPEP	LIPASE/PROTEASE/AMYLASE	25,000 UNIT-79,000 UNIT-105,000 UNIT	New Strength
ANTIDIURETIC AND VASOPRESSOR HORMONES	NOCTIVA	DESMOPRESSIN ACETATE	0.83/SPRAY	New Strength
ANTIDIURETIC AND VASOPRESSOR HORMONES	NOCTIVA	DESMOPRESSIN ACETATE	1.66/SPRAY	New Strength
PREGNANCY MAINTAINING AGENT,HORMONAL	MAKENA	HYDROXYPROGESTERONE CAPROAT/PF	275 MG/1.1 AUTOINJECT -OR	New Strength and Dosage Form
TOPICAL ANTI-INFLAMMATORY, NSAIDS	DITHOL	DICLOFENAC SODIUM/MENTHOL	1.5 %-10 %	New Combination
ANTINEOPLASTIC SYSTEMIC ENZYME INHIBITORS	IMBRUVICA	IBRUTINIB	140 MG	New Dosage Form
ANTINEOPLASTIC SYSTEMIC ENZYME INHIBITORS	IMBRUVICA	IBRUTINIB	280 MG	New Strength and Dosage Form
ANTINEOPLASTIC SYSTEMIC ENZYME INHIBITORS	IMBRUVICA	IBRUTINIB	420 MG	New Strength and Dosage Form
ANTINEOPLASTIC SYSTEMIC ENZYME INHIBITORS	IMBRUVICA	IBRUTINIB	560 MG	New Strength and Dosage Form
ANTINEOPLASTIC SYSTEMIC ENZYME INHIBITORS	IMBRUVICA	IBRUTINIB	70 MG	New Strength
ANTIEMETIC/ANTIVERTIGO AGENTS	BONJESTA	DOXYLAMINE SUCCINATE/ VIT B6	20 MG-20 MG	New Strength and Dosage Form

DESCRIPTION	BRAND NAME	GENERIC NAME	STRENGTH	NOTES
EYE ANTIBIOTIC, GLUCOCORTICOID AND NSAID COMB	PREDNISOLONE -GATIFLOX-BROMFENC	GATIFLOXACIN/PREDNIS/BROM FENAC	0.5 %-1 %-0.075 %	New Combination, no pricing, claims will not adjudicate until pricing is added
VANCOMYCIN ANTIBIOTICS AND DERIVATIVES	FIRVANQ	VANCOMYCIN HCL	25 MG/ML	New Strength
ARTV NUCLEOSIDE,NUCLEOTIDE,N ON-NUCLEOSIDE RTI COMB	SYMFI LO	EFAVIRENZ/LAMIVU/TENOFOV DISOP	400-300 MG	New Combination
PHOSPHODIESTERASE-4 (PDE4) INHIBITORS	DALIRESP	ROFLUMILAST	250 MCG	New Strength

NEW INDICATIONS (EXISTING DRUGS)

ADCETRIS®

March 20, 2018

Seattle Genetics, Inc. (Nasdaq: SGEN) announced today that the U.S. Food and Drug Administration (FDA) has approved ADCETRIS (brentuximab vedotin) in combination with chemotherapy in adult patients with previously untreated Stage III or IV classical Hodgkin lymphoma. The approval is based on the successful outcome of the phase 3 ECHELON-1 clinical trial that compared ADCETRIS plus AVD (Adriamycin, vinblastine and dacarbazine) to ABVD (Adriamycin, bleomycin, vinblastine and dacarbazine). In addition, data from the ECHELON-1 trial converted the U.S. accelerated approval of ADCETRIS for the treatment of adults with systemic anaplastic large cell lymphoma (sALCL) after failure of at least one multi-agent chemotherapy regimen to regular approval. In October 2017, the FDA granted Breakthrough Therapy Designation (BTD) to ADCETRIS in combination with chemotherapy for the frontline treatment of patients with advanced classical Hodgkin lymphoma. The FDA also granted Priority Review for the supplemental Biologics License Application (BLA), and the Prescription Drug User Fee Act (PDUFA) target action date was May 1, 2018.

Source: Seattle Genetics, Inc.

Hizentra®

March 16, 2018

Global biotherapeutics leader CSL Behring today announced that the U.S. Food and Drug Administration (FDA) approved Hizentra® (Immune Globulin Subcutaneous [Human] 20% Liquid) as the first and only subcutaneous immunoglobulin (SCIg) for the treatment of chronic inflammatory demyelinating polyneuropathy (CIDP) as maintenance therapy to prevent relapse of neuromuscular disability and impairment. The approval was based on data from the Phase III PATH (Polyneuropathy And Treatment with Hizentra) study, which is the largest controlled clinical study in CIDP patients to date. CIDP is a rare autoimmune disorder that affects the peripheral nerves and may cause permanent nerve damage.

Source: CSL Behring

OTIPRIO®

March 2, 2018

SAN DIEGO, March 02, 2018 (GLOBE NEWSWIRE) --Otonomy, Inc. (NASDAQ:OTIC), a biopharmaceutical company dedicated to the development of innovative therapeutics for otology, today announced that the U.S. Food and Drug Administration (FDA) has approved OTIPRIO (ciprofloxacin otic suspension) 6% for the treatment of acute otitis externa (AOE) in patients 6 months of age and older due to *Pseudomonas aeruginosa* and *Staphylococcus aureus*. OTIPRIO is the first single-dose antibacterial approved by the FDA for treating AOE.

Source: Otonomy, Inc.

Verzenio™

February 26, 2018

INDIANAPOLIS, Feb. 26, 2018 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) today announced that the U.S. Food and Drug Administration (FDA) has approved Verzenio™ (abemaciclib) in combination with an aromatase inhibitor (AI) as initial endocrine-based therapy for the treatment of postmenopausal women with hormone receptor-positive (HR+), human epidermal growth factor receptor 2-negative (HER2-) advanced or metastatic breast cancer. This additional FDA approval marks the third indication for Verzenio within five months. In September 2017, Verzenio became the first and only cyclin dependent kinase (CDK)4 & 6 inhibitor approved in combination and as a single agent in metastatic breast cancer. Specifically, Verzenio was approved for use in combination with fulvestrant for the treatment of women with HR+, HER2- advanced or metastatic breast cancer with disease progression following endocrine therapy, and as

monotherapy for the treatment of adult patients with HR+, HER2- advanced or metastatic breast cancer with disease progression following endocrine therapy and prior chemotherapy in the metastatic setting.

Source: Eli Lilly

LUZU®

February 22, 2018

RALEIGH, N.C., FEBRUARY 22, 2018 – Ortho Dermatologics, a division of Valeant Pharmaceuticals North America, LLC (NYSE: VRX and TSX: VRX) (“Valeant”), today announced that the U.S. Food and Drug Administration (FDA) approved the supplemental New Drug Application (sNDA) to expand the use of LUZU® (luliconazole) cream, 1% for the topical treatment of patients 12 and older with athlete's foot (interdigital tinea pedis) and jock itch (tinea cruris) and patients two and older with ringworm (tinea corporis), caused by the organisms *Trichophyton rubrum* and *Epidermophyton floccosum*. These conditions are very common skin diseases caused predominantly by dermatophyte fungi. LUZU was initially approved as a treatment for adults in 2013.

Source: Ortho Dermatologics

FDA NEWS/BULLETINS/ADVISORIES/SAFETY ALERTS

Labetalol Hydrochloride Injection by Hospira: Recall - Potential For Cracked Glass At Rim Surface Of Vials [Posted 2/23/2018]

ISSUE: Hospira is voluntarily recalling 3 lots of Labetalol Hydrochloride Injection, USP, 100 mg/20 mL Vial (NDC 0409-2267-20), and one lot of Labetalol Hydrochloride Injection, USP, Novaplus (NDC 0409-2267-25) to the hospital/institution level. Hospira, Inc. initiated this recall due to the discovery of cracks on the rim surface of vials for these lots, which is covered by the stopper and crimp seal. Cracked vials may result in a lack of sterility assurance for the product. Use of or exposure to a nonsterile product may be associated with adverse events such as fever, chills, sepsis or invasive systemic infections in patients. Product was distributed nationwide to wholesalers / retailers / hospitals in the United States and Puerto Rico from April 2017 to August 2017.

BACKGROUND: Labetalol Hydrochloride is an adrenergic receptor blocking agent indicated for the control of blood pressure (BP) in severe hypertension. It is administered by repeated intravenous (IV) injections or by slow IV infusion.

RECOMMENDATION: Hospira, Inc. has notified wholesalers/retailers/hospitals by recall letter to arrange for return of any recalled product. Wholesalers/retailers/hospitals/institutions with an existing inventory of the lots subject to this recall should stop use and distribution of the remaining units and quarantine immediately. Healthcare Professionals in your organization should be informed 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)

Bella Diet Capsules by Bella All Natural: Recall - Presence of Sibutramine [Posted 2/27/2018]

ISSUE: Bella All Natural is voluntarily recalling its Diet Capsules labeled as Bella, Lot Number MFD: 10.15.2017 EXP: 10.14.2019, to the consumer level. This recall has been initiated due to presence of sibutramine. Sibutramine is an appetite suppressant that was withdrawn from the U.S. market in October 2010 due to safety concerns. N-Desmethyl sibutramine is an active metabolite of sibutramine. Sibutramine and its active metabolites substantially increase blood pressure and/or pulse rate in some patients and may present significant health risks including heart attack, arrhythmia, and stroke.

BACKGROUND: The product is used as a diet pill and is packaged in a plastic bottle, with 30 pills, and with the Lot Number MFD: 10.15.2017 EXP: 10.14.2019. Bella was distributed in California via internet and retail.

RECOMMENDATION: Bella All Natural is notifying its distributors and customers by Customer Notification/Recall Communication and is arranging for return of product of all recalled products. Consumers that have Bella Diet Capsules which is being recalled should stop using immediately and return to place of purchase. Consumers with questions regarding this recall can contact Bella all Natural by calling (323) 552-6263, or e-mail address: cabral_daisy@yahoo.com on Monday-Sunday, 10 a.m. - 5:30 p.m., PST. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Source: Department of Health and Human Services

Compounded Drug Products From Cantrell Drug Company: FDA Warning - Serious Deficiencies In Quality And Sterility Assurance

[Posted 3/2/2018]

ISSUE: FDA is alerting health care professionals and patients not to use drug products produced by Cantrell Drug Company of Little Rock, Arkansas, including opioid products and other drugs intended for sterile injection that were produced by the company and distributed nationwide. The agency is concerned about serious deficiencies in Cantrell's compounding operations, including its processes to ensure quality and sterility assurance that put patient safety at risk. Administration of contaminated or otherwise poor quality drug products can result in serious and life-threatening injury or death. The FDA has also sought legal action to prevent the company from further producing and distributing drugs. In a preliminary injunction filed in the U.S. District Court in the Eastern District of Arkansas, the Department of Justice, in conjunction with the FDA, asked the court to order Cantrell to stop manufacturing, processing, packing, labeling, holding and/or distributing any drugs until the company complies with the Federal Food, Drug, and Cosmetic Act (FD&C Act) and its implementing regulations. The proposed order also will require Cantrell to recall all non-expired drug products on the market.

BACKGROUND: FDA investigators most recently inspected Cantrell's facility in June 2017, and observed poor compounding drug operations. Of particular concern, the FDA investigators observed insanitary conditions and violations of current Good Manufacturing Practice (CGMP) that could cause Cantrell's drugs to become contaminated or made injurious to health. Because Cantrell produces drugs that are intended for sterile injection, the conditions identified — which can expose such products to contamination and render them unsterile — raise significant public health concerns. In response to the FDA's recommendation, in July 2017, Cantrell recalled all drug products marketed as sterile and ceased sterile compounding. However, against FDA advice, the company resumed production and distribution without demonstrating that it had adequately addressed the problems identified.

RECOMMENDATION: Health care professionals should immediately check their medical supplies, quarantine any drug products from Cantrell Drug Company and not administer them to patients. The FDA urges health care professionals who obtained products from Cantrell to make alternative arrangements to obtain medications they administer or dispense to patients from sources that adhere to proper quality standards. Patients who have received any drug product produced by Cantrell and have concerns should contact their health care professional.

Source: Department of Health and Human Services

Alka-Seltzer Plus Products: Recall - Ingredients on Front Sticker May Not Match Product in Carton

[Posted 3/16/2018]

ISSUE: Bayer is voluntarily recalling Alka-Seltzer Plus packages that were sold only in the U.S. at Walmart, CVS, Walgreens and Kroger (including Dillons Food Stores, Fred Meyer, Fry's Food Stores, Ralphs, King Soopers and Smith's Food and Drug) after February 9, 2018. Products can be identified by checking the Bayer logo located on the lower left corner of the front of the carton. If the logo has an orange or green background, the product is included in the recall. The affected packages are being recalled because the ingredients on the front sticker may not match the actual product in the carton. The ingredients listed on the front sticker of the carton may potentially be different from the ingredients listed on the back of the carton. This may lead consumers to ingest a product to which they may have an allergy or anaphylactic reaction, an ingredient which may be contraindicated for their medical condition or they intend to otherwise avoid. There may be potential for serious health consequences.

BACKGROUND: The Alka-Seltzer Plus products subject to the recall are intended to temporarily relieve symptoms associated with cold and flu, such as cough, congestion, fever and/or mucus.

RECOMMENDATION: Consumers who purchased packages of Alka-Seltzer Plus that are being recalled should stop using the product and contact Bayer with questions, to report any issues experienced or for instructions about how to receive a refund. Consumers with questions about this recall can contact Bayer Consumer Relations at: 1-800-986-0369 (available Monday - Friday 9:00 AM - 5:00 PM ET). Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

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

STUDIES AND RECENT TOPICS

One Gout Medication Comes Out on Top for CV Risk

February 26, 2018

A retrospective comparison of two established gout medications suggested that patients receiving probenecid (Probalan) have a lower cardiovascular risk than peers on the standard therapy of allopurinol (Zyloprim), researchers reported from a government-funded study.

Source: medpagetoday.com

Hormonal Birth Control Won't Raise Depression Risk: Study

February 26, 2018

There's no evidence of a link between hormonal birth control and depression in women, researchers report. "Depression is a concern for a lot of women when they're starting hormonal contraception, particularly when they're using specific types that have progesterone," study lead author Dr. Brett Worly said in a news release from Ohio State University's Wexner Medical Center.

Source: healthday.com

CLL Responds To Induction With RCC Regimen Plus Rituximab Maintenance

February 27, 2018

There was a high rate of response among patients with previously untreated chronic lymphocytic leukemia (CLL) who underwent induction treatment with the renal cell carcinoma (RCC) regimen cladribine, cyclophosphamide, and rituximab followed by maintenance with rituximab compared with maintenance observation alone, results of the PALG-CLL4 trial show.

Source: cancernetwork.com

Two-Drug Tx On Par With Standard Care In Complex UTI

February 27, 2018

Meropenem-vaborbactam, a combination medication for certain types of drug-resistant infections, was comparable to piperacillin-tazobactam, for treating complicated urinary tract infections (UTI), researchers reported

Source: medpagetoday.com

Metformin In Pregnancy Tied To Heavier Toddlers

February 27, 2018

Children born of mothers with polycystic ovarian syndrome who took metformin during pregnancy were more likely to have weight issues as toddlers, follow-up of two trials showed. Women randomized to metformin for gestational diabetes delivered children who weighed more (mean difference in z-score 0.38, 95% CI 0.07-0.69, P=0.017) and had higher BMI (0.45, 0.11-0.78, P=0.010) at age 4 years.

Source: medpagetoday.com

Regeneron's Eylea Inflammation Risk Tied To Drug Syringes

February 28, 2018

Regeneron Pharmaceuticals Inc. said an extensive investigation into a rare and frightening side effect seen in clusters of patients getting its best-selling drug Eylea has been tied to syringes used to inject the medicine into the eye.

Source: bloomberg.com

HIV Patients With Depression Face Serious Risks

March 1, 2018

The proportion of time patients with HIV spend depressed is directly related to their likelihood of missing doctor appointments, how well their infection is suppressed and their risk of death from any cause, according to a multi-site U. S. study.

Source: reuters.com

FDA: Clarithromycin Risky For Patients With Heart Disease

March 1, 2018

On Feb. 22, the FDA issued a safety announcement (www.fda.gov) on prescribing clarithromycin (Biaxin) to patients with heart disease because of an increase in the risk of cardiac and cerebrovascular events and even death that can occur years later. This recommendation is based on the FDA's review of 10 years of follow-up data (www.ctu.dk) from the large CLARICOR clinical trial (www.ncbi.nlm.nih.gov) involving short-term clarithromycin use in patients with stable coronary heart disease. It was during that initial placebo-controlled trial that these adverse events were first observed.

Source: healio.com

Merck Turns To Tumor-Killing Viruses To Boost Immune Cancer Drugs

March 1, 2018

Scientists have tried to muster viruses to hunt and kill tumors for almost 70 years, with limited success. That may be changing. Now, microbes are playing an important role in an emerging branch of cancer immunotherapy that's attracting some of the world's biggest drug makers. Merck announced plans to buy Australia's Vivalytics Ltd. last week to gain an experimental cold virus-based treatment that may bolster the utility of Keytruda, its blockbuster cancer medicine.

Source: bloomberg.com

Long-Term Inhaled Corticosteroid Use Linked To Hip Fracture Risk

March 5, 2018

Patients who used long-term inhaled corticosteroids to treat their COPD were at moderately higher risk for upper extremity and hip fractures, according to findings published in *Chest*. "Inhaled corticosteroids are known to reduce bone mineral density, but whether their use increases the risk of fractures is less clear," told Anne V. Gonzalez, MD, of the respiratory epidemiology and clinical research unit at the Montreal Chest Institute. "In particular, few studies previously examined the effect of long-term inhaled corticosteroid use on risk of fracture, and none looked at the risk in postmenopausal women vs. men."

Source: healio.com

Chronic Oral Glucocorticoid Use In Pediatric Asthma May Increase Morbidities

March 5, 2018

Children with asthma who were treated with chronic oral glucocorticoids experienced significant morbidities, including adrenal suppression, recurrent pneumonia, and behavioral problems, according to research presented at the 2018 Joint Congress of the American Academy of Allergy, Asthma & Immunology and World Allergy Organization (AAAAI/WAO) in Orlando, Florida.

Source: pulmonologyadvisor.com

Miracle Of Hemophilia Drugs Comes At A Steep Price

March 5, 2018

When Landon Morris was diagnosed with hemophilia shortly after birth, his mother, Jessica Morris, was devastated. "It was like having your dreams — all the dreams you imagined for your child — just kind of disappear," she recalled.

Source: npr.org

23andme Scores FDA Nod For First DTC Genetic Test On Cancer Risk

March 6, 2018

Staying ahead of the curve on direct-to-consumer (DTC) genetic health risk (GHR) assessments, 23andMe became the first company with US Food and Drug Administration (FDA) marketing authorization for three cancer-associated variants.

Source: raps.org

Good Adherence Seen With Anti-HIV Vaginal Ring

March 7, 2018

Women who participated in an open-label extension trial of the dapivirine-eluting vaginal ring for prevention of human immunodeficiency virus (HIV) infection used the device often enough to have reduced the risk of contracting the virus which causes AIDS by 54%, researchers suggested here.

Source: medpagetoday.com

Slow-Release Hydrogel Aids Immunotherapy For Cancer

March 8, 2018

An immunotherapy drug embedded in a slow-release hydrogel invented at Rice University in collaboration with the University of Texas Health Science Center at Houston (UTHealth) appears to be highly effective at killing cancer cells.

Source: eurekalert.org

Cutting Chemo Heart Risks for Breast Cancer Patients**March 12, 2018**

Two classes of blood pressure drugs show promise in preventing heart complications caused by chemotherapy for breast cancer, researchers report. One in four women who receives the chemo drug Herceptin develops potentially dangerous heart problems. However, the drug is highly effective at treating an aggressive form of breast cancer called HER2-positive, the scientists added.

Source:healthday.com

Abiraterone, Docetaxel Best With ADT for Metastatic Prostate Cancer**March 19, 2018**

A meta-analysis suggests that abiraterone acetate plus prednisolone/prednisone (AAP) may be the most effective therapy added to androgen deprivation therapy (ADT) for men with metastatic hormone-naive prostate cancer (mHNPc). The results also supported the use of docetaxel along with ADT.

Source:cancernetwork.com

Montelukast Eases Asthma Symptoms in Youngest Patients**March 19, 2018**

Preschool children who received daily montelukast (Singulair) experienced fewer asthma symptom exacerbations than those receiving an as-needed beta 2-agonist bronchodilator, in a randomized controlled trial of treatment for early stage asthma.

Source:mdmag.com

Birth control pill for men shows promise in early study**March 20, 2018**

A small, recently released study shows a newly developed oral contraceptive for men appears to be both effective and safe. The research, presented at the Endocrine Society's annual meeting in Chicago by researchers from the University of Washington in Seattle, studied 83 men between the ages of 18 and 50. The participants' testosterone levels dropped significantly along with two hormones essential for sperm production.

Source:cnbc.com

RECALLS

Product Type	Product Description	Class	Code Info	Reason for Recall	Recalling Firm
Drugs	GERICARE Eyewash, sterile eye irrigating solution, packaged in a 4 fl oz (118 mL) bottle, OTC, Distributed by Geri-Care Pharmaceuticals Corp., Brooklyn, NY 11204, NDC 57896-0186-04	Class I	Lot #: 86041601, Exp 09/19	Non-sterility: confirmed microbial contamination with <i>Achromobacter xylosoxidans</i>	Kareway Product Inc
Drugs	Bella Capsules, 600mg, 30-count bottles, Manufactured for: Bella All Natural 304 E 11th Street, Los Angeles, CA 90015	Class I	Lot #: MFD:10.15.2017, Exp.10/14/2019.	Marketed Without An Approved NDA/ANDA: This product contains undeclared sibutramine. The presence of sibutramine, a previously approved controlled substance that was withdrawn from the U.S. market in October 2010 due to safety concerns, in this tainted product renders it an unapproved drug for which safety and efficacy have not been established and therefore subject to recall.	Bella All Natural
Drugs	Hydromorphone, Hydrochloride, Injection, USP CII, 10 mg/mL, Rx Only, 1 mL Single-dose Vial, High Potency Formulation. Mfd For: Teva Parenteral Medicines, Inc., Irvine, CA 92618. NDC: 0703-0110-01	Class I	Lots # 691853F, EXP. 9/1/2018; 700753F, EXP. 10/1/2018.	Non-Sterility: Confirmed customer complaints of glass product container vials that may be empty or cracked.	Pfizer Inc.

Product Type	Product Description	Class	Code Info	Reason for Recall	Recalling Firm
Drugs	Hydromorphone, Hydrochloride, Injection, USP CII, 10 mg/mL, Rx Only, 1 mL Single-dose Vial, High Potency Formulation. Hospira, Inc., Lake forest, IL 60045 USA. NDC: 0409-2634-01	Class I	Lot 71330DD EXP. 11/1/2018.	Non-Sterility: Confirmed customer complaints of glass product container vials that may be empty or cracked.	Pfizer Inc.
Drugs	HYDROMORPHONE HCl in Sodium Chloride 0.9% in all doses, all strengths, and all packaging.	Class II	All lots remaining within expiry.	Lack of sterility assurance.	Pharmedium Services, LLC
Drugs	Bupivacaine HCl in 0.9% Sodium Chloride in all doses, all strengths, and packaging.	Class II	All lots remaining within expiry.	Lack of sterility assurance.	Pharmedium Services, LLC
Drugs	Fentanyl Citrate and Ropivacaine HCl in 0.9% Sodium Chloride in all strengths, all doses, and all packaging.	Class II	All lots remaining within expiry.	Lack of sterility assurance.	Pharmedium Services, LLC
Drugs	Fentanyl Citrate and Bupivacaine HCl in 0.9% Sodium Chloride in all strengths, all doses, and all packaging.	Class II	All lots remaining within expiry.	Lack of sterility assurance.	Pharmedium Services, LLC
Drugs	Ephedrine Sulfate in 0.9% Sodium Chloride in all strengths, all doses, and all packaging.	Class II	All lots remaining within expiry.	Lack of sterility assurance.	Pharmedium Services, LLC

Product Type	Product Description	Class	Code Info	Reason for Recall	Recalling Firm
Drugs	HYDROMorphone HCl Injection in all strengths, all doses, and all packaging.	Class II	All lots remaining within expiry.	Lack of sterility assurance.	Pharmedi um Services, LLC
Drugs	Midazolam HCl in 0.9% Sodium Chloride in all strengths, all doses, and all packaging.	Class II	All lots remaining within expiry.	Lack of sterility assurance.	Pharmedi um Services, LLC
Drugs	Midazolam HCl in 5% Dextrose in all strengths, all doses, and all packaging.	Class II	All lots remaining within expiry.	Lack of sterility assurance.	Pharmedi um Services, LLC
Drugs	Morphine Sulfate in 0.9% Sodium Chloride in all strengths, all doses, and all packaging.	Class II	All lots remaining within expiry.	Lack of sterility assurance.	Pharmedi um Services, LLC
Drugs	Morphine Sulfate in 5% Dextrose in all strengths, all doses, and all packaging.	Class II	All lots remaining within expiry.	Lack of sterility assurance.	Pharmedi um Services, LLC
Drugs	Lidocaine HCl in all strengths, all doses, and all packaging.	Class II	All lots remaining within expiry.	Lack of sterility assurance.	Pharmedi um Services, LLC
Drugs	Fentanyl Citrate in 0.9% Sodium Chloride in all strengths, all doses, and all packaging.	Class II	All lots remaining within expiry.	Lack of sterility assurance.	Pharmedi um Services, LLC
Drugs	Potassium Chloride in 0.9% Sodium Chloride in all strengths, all doses, and all packaging.	Class II	All lots remaining within expiry.	Lack of sterility assurance.	Pharmedi um Services, LLC

Product Type	Product Description	Class	Code Info	Reason for Recall	Recalling Firm
Drugs	Ketamine HCl in 0.9% Sodium Chloride in all strengths, all doses, and all packaging.	Class II	All lots remaining within expiry.	Lack of sterility assurance.	Pharmedium Services, LLC
Drugs	Succinylcholine Chloride in all strengths, all doses, and all packaging.	Class II	All lots remaining within expiry.	Lack of sterility assurance.	Pharmedium Services, LLC
Drugs	Adenosine Injection in all strengths, all doses, and all packaging.	Class II	All lots remaining within expiry.	Lack of sterility assurance.	Pharmedium Services, LLC
Drugs	Dexamethasone Sodium Phosphate in all strengths, all doses, and all packaging.	Class II	All lots remaining within expiry.	Lack of sterility assurance.	Pharmedium Services, LLC
Drugs	Phenylephrine HCl in 0.9% Sodium Chloride in all strengths, all doses, and all packaging.	Class II	All lots remaining within expiry.	Lack of sterility assurance.	Pharmedium Services, LLC
Drugs	Potassium Chloride in 5% Dextrose in all strengths, all doses, and all packaging.	Class II	All lots remaining within expiry.	Lack of sterility assurance.	Pharmedium Services, LLC
Drugs	Labetalol HCl in all strengths, all doses, and all packaging.	Class II	All lots remaining within expiry.	Lack of sterility assurance.	Pharmedium Services, LLC
Drugs	Methadone HCl in 0.9% Sodium Chloride in all strengths, all doses, and all packaging.	Class II	All lots remaining within expiry.	Lack of sterility assurance.	Pharmedium Services, LLC

Product Type	Product Description	Class	Code Info	Reason for Recall	Recalling Firm
Drugs	Midazolam HCl Injection in all strengths, all doses, and all packaging.	Class II	All lots remaining within expiry.	Lack of sterility assurance.	Pharmedi um Services, LLC
Drugs	Fentanyl Citrate Injection in all strengths, all doses, and all packaging.	Class II	All lots remaining within expiry.	Lack of sterility assurance.	Pharmedi um Services, LLC
Drugs	Ephedrine Sulfate Injection in all strengths, all doses, and all packaging.	Class II	All lots remaining within expiry.	Lack of sterility assurance.	Pharmedi um Services, LLC
Drugs	Ketamine HCl Injection in all strengths, all doses, and all packaging.	Class II	All lots remaining within expiry.	Lack of sterility assurance.	Pharmedi um Services, LLC
Drugs	Ropivacaine HCl in 0.9% Sodium Chloride in all strengths, all doses, and all packaging.	Class II	All lots remaining within expiry.	Lack of sterility assurance.	Pharmedi um Services, LLC
Drugs	Glycopyrrolate in all strengths, all doses, and all packaging.	Class II	All lots remaining within expiry.	Lack of sterility assurance.	Pharmedi um Services, LLC
Drugs	Lidocaine HCl in 0.9% Sodium Chloride in all strengths, all doses, and all packaging.	Class II	All lots remaining within expiry.	Lack of sterility assurance.	Pharmedi um Services, LLC
Drugs	Atropine Sulfate Injection in all strengths, all doses, and all packaging.	Class II	All lots remaining within expiry.	Lack of sterility assurance.	Pharmedi um Services, LLC

Product Type	Product Description	Class	Code Info	Reason for Recall	Recalling Firm
Drugs	HYDROMorphone HCl in 5% Dextrose in all strengths, all doses, and all packaging.	Class II	All lots remaining within expiry.	Lack of sterility assurance.	Pharmedi um Services, LLC
Drugs	Ropivacaine HCl Injection in all strengths, all doses, and all packaging.	Class II	All lots remaining within expiry.	Lack of sterility assurance.	Pharmedi um Services, LLC
Drugs	Nicardipine HCl in all strengths, all doses, and all packaging.	Class II	All lots remaining within expiry.	Lack of sterility assurance.	Pharmedi um Services, LLC
Drugs	Labetalol HCl in 0.9% Sodium Chloride in all strengths, all doses, and all packaging.	Class II	All lots remaining within expiry.	Lack of sterility assurance.	Pharmedi um Services, LLC
Drugs	Neostigmine Methylsulfate Injection in all strengths, all doses, and all packaging.	Class II	All lots remaining within expiry.	Lack of sterility assurance.	Pharmedi um Services, LLC
Drugs	Vecuronium Bromide in Sterile Water for Injection in all strengths, all doses, and all packaging.	Class II	All lots remaining within expiry.	Lack of sterility assurance.	Pharmedi um Services, LLC
Drugs	Dexamethasone Sodium Phosphate added to 0.9% Sodium Chloride in all strengths, all doses, and all packaging.	Class II	All lots remaining within expiry.	Lack of sterility assurance.	Pharmedi um Services, LLC
Drugs	Esmolol HCl in all strengths, all doses, and all packaging.	Class II	All lots remaining within expiry.	Lack of sterility assurance.	Pharmedi um Services, LLC

Product Type	Product Description	Class	Code Info	Reason for Recall	Recalling Firm
Drugs	Meperidine HCl in 0.9% Sodium Chloride in all strengths, all doses, and all packaging.	Class II	All lots remaining within expiry.	Lack of sterility assurance.	Pharmedi um Services, LLC
Drugs	Methadone HCl Injection in all strengths, all doses, and all packaging.	Class II	All lots remaining within expiry.	Lack of sterility assurance.	Pharmedi um Services, LLC
Drugs	Rocuronium Bromide in all strengths, all doses, and all packaging.	Class II	All lots remaining within expiry.	Lack of sterility assurance.	Pharmedi um Services, LLC
Drugs	Dexamethasone Sodium Phosphate added to 5% Dextrose in all strengths, all doses, and all packaging.	Class II	All lots remaining within expiry.	Lack of sterility assurance.	Pharmedi um Services, LLC
Drugs	Nicardipine HCl in 0.9% Sodium Chloride in all strengths, all doses, and all packaging.	Class II	All lots remaining within expiry.	Lack of sterility assurance.	Pharmedi um Services, LLC

Product Type	Product Description	Class	Code Info	Reason for Recall	Recalling Firm
Drugs	Amitriptyline HCl USP for prescription compounding, packaged in a) 25 g (NDC 58597-8003-4); b) 100 g (NDC 58597-8003-6); c) 500 g (NDC 58597-8003-7), d) 1000 g (NDC 58597-8003-8), RX only, packed by American Pharmaceutical Ingredients, 6650 Highland Road, Waterford, MI 48327.	Class II	Lot #: a) 031915-1, Exp. 12/31/2019; b) 031915-2, Exp. 12/31/2019; c) 031915-2, Exp. 12/31/2019; d) 031915-1, Exp. 12/31/2019.	CGMP Deviations: Lack of stability data and controls to support the manufacturer's assigned retest or expiration date in firm's container/closure system.	American Pharmaceutical Ingredients LLC
Drugs	Anastrozole USP for prescription compounding, packaged in a) 1g (NDC 58597-8080-1), b) 5g (NDC 58597-8080-2), c) 25g (NDC 58597-8080-4), RX only, packed by American Pharmaceutical Ingredients, 6650 Highland Road, Waterford, MI 48327.	Class II	Lot #: a) 011116-1, Exp. 07/31/2020; b) 011116-1, 011116-2, Exp. 07/31/2020; c) 011116-1, Exp. 07/31/2020	CGMP Deviations: Lack of stability data and controls to support the manufacturer's assigned retest or expiration date in firm's container/closure system.	American Pharmaceutical Ingredients LLC

Product Type	Product Description	Class	Code Info	Reason for Recall	Recalling Firm
Drugs	Baclofen USP (Micronized) for prescription compounding, packaged in a) 25g (NDC 58597-8004-4); b)100g (NDC 58597-8004-6); c) 500g (NDC 58597-8004-7); d) 1000g (NDC 58597-8004-8), RX only, packed by American Pharmaceutical Ingredients, 6650 Highland Road, Waterford, MI 48327.	Class II	Lot #: a) 021816-2, 021816-3, Exp. 08/24/2018; 70616-1, Exp. 01/31/2019; b) 021816-1, Exp. 08/24/2018; 070616-1, Exp. 01/31/2019; c) 021816-1, Exp. 08/24/2018; 070616-1, Exp. 01/31/2019; d) 021816-1, Exp. 08/24/2018; 070616-1, exp. 01/31/2019.	CGMP Deviations: Lack of stability data and controls to support the manufacturer’s assigned retest or expiration date in firm's container/closure system.	American Pharmaceutical Ingredients LLC
Drugs	Calcipotriene BP (Monohydrate) for prescription compounding, packaged in a) 250mg (NDC 58597-8630-1); b) 500mg (NDC 58597-8630-2); c) 1g (NDC 58597-8630-3), Rx only, packed by American Pharmaceutical Ingredients, 6650 Highland Road, Waterford, MI 48327.	Class II	Lot #: a) 050715-2, Exp. 04/30/2019; b) 050715-2, Exp. 04/30/2019; c) 050715-1, Exp. 04/30/2019.	CGMP Deviations: Lack of stability data and controls to support the manufacturer’s assigned retest or expiration date in firm's container/closure system.	American Pharmaceutical Ingredients LLC

Product Type	Product Description	Class	Code Info	Reason for Recall	Recalling Firm
Drugs	Celecoxib USP for prescription compounding, packaged in a) 25g (NDC 58597-8635-4); b) 100g (NDC 58597-8635-5); c) 1000g (NDC 58597-8635-7), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327	Class II	Lot #: a) 080515-2, Exp. 06/05/2019; b) 080515-1, Exp. 06/05/2019; c) 080515-1, Exp. 06/05/2019;	CGMP Deviations: Lack of stability data and controls to support the manufacturer's assigned retest or expiration date in firm's container/closure system.	American Pharmaceutical Ingredients LLC
Drugs	Clindamycin Phosphate USP for prescription compounding, packaged in a) 10g (NDC 58597-8198-3); b) 100g (NDC 58597-8198-6), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327	Class II	Lot #: a) 042315-1, Exp. 03/12/2018; b) 042315-1, Exp. 03/12/2018	CGMP Deviations: Lack of stability data and controls to support the manufacturer's assigned retest or expiration date in firm's container/closure system.	American Pharmaceutical Ingredients LLC

Product Type	Product Description	Class	Code Info	Reason for Recall	Recalling Firm
Drugs	Clonidine HCl USP for prescription compounding, packaged in a) 5g (NDC 58597-8010-2); b) 10g (NDC 58597-8010-3); c) 25g (NDC 58597-8010-4); d)100g (NDC 58597-8010-6), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327	Class II	Lot #: a) 070915-1, Exp. 12/31/2019; b) 070915-1, Exp. 12/31/2019; c) 070915-1, Exp. 12/31/2019; d) 070915-1, Exp. 12/31/2019	CGMP Deviations: Lack of stability data and controls to support the manufacturer's assigned retest or expiration date in firm's container/closure system.	American Pharmaceutical Ingredients LLC
Drugs	Cyclobenzaprine HCl USP for prescription compounding, packaged in a) 25g (NDC 58597-8011-4), b)100g (NDC 58597-8011-6); c) 500 g (NDC 58597-8011-7); d)1000g (NDC 58597-8011-8), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327	Class II	Lot #: a) 081715-1, Exp. 2/29/2020; b) 010615-1, Exp. 6/30/2019; 051616-1, Exp.11/30/2020; 081715-1, Exp. 2/29/2020; CBP1307004BV P-4102015, Exp. 4/30/2018; c) 010615-1, Exp. 6/30/2019; 081715-1, Exp. 2/29/2020 d) 010615-1, Exp. 6/30/2019; 051616-1, Exp.11/30/2020; 081715-1, Exp. 2/29/2020; 081715-2, Exp. 2/29/2020;	CGMP Deviations: Lack of stability data and controls to support the manufacturer's assigned retest or expiration date in firm's container/closure system.	American Pharmaceutical Ingredients LLC

Product Type	Product Description	Class	Code Info	Reason for Recall	Recalling Firm
Drugs	Cyclosporine USP, for prescription compounding, packaged in a) 5g (NDC 58597-8210-2); b) 10g (NDC 58597-8210-3); c) 100g, NDC 58597-8210-6; d) 500g (NDC 58597-8210-7), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327	Class II	Lot #: a) 062515-2, Exp. 02/28/2019; b) 062515-1, Exp. 02/28/2019; 062515-2, Exp. 02/28/2019; 052317B-2, Exp. 01/31/2021; c) 052317B-1, Exp. 01/31/2021; 052317B-1, Exp. 01/31/2021; 062515-1, exp. 02/28/2019; d) 052317B-1, Exp. 01/31/2021; 062515-3, exp. 02/28/2019.	CGMP Deviations: Lack of stability data and controls to support the manufacturer's assigned retest or expiration date in firm's container/closure system.	American Pharmaceutical Ingredients LLC
Drugs	Desoximetasone USP (Micronized) for prescription compounding, 5g, RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327, NDC 58597-8634-2.	Class II	Lot #: 071015-1, Exp. 3/7/2018	CGMP Deviations: Lack of stability data and controls to support the manufacturer's assigned retest or expiration date in firm's container/closure system.	American Pharmaceutical Ingredients LLC

Product Type	Product Description	Class	Code Info	Reason for Recall	Recalling Firm
Drugs	Diclofenac Sodium USP for prescription compounding, packaged in a) 25g (NDC 58597-8012-4); b)100g (NDC 58597-8012-6); c) 500 g (NDC 58597-8012-7); d) 1000g (NDC 58597-8012-8), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327	Class II	Lot #: a) 082715-1, Exp. 06/24/2018; 061715-1, Exp. 6/6/2018; 072516-2, Exp. 07/04/2019; b) 082715-1, Exp. 06/24/2018; 061715-1, Exp. 6/6/2018; 072516-2, Exp. 07/04/2019; c) 061715-1, Exp. 6/6/2018; 072516-2, Exp. 07/04/2019; 082715-1, Exp. 06/24/2018; d) 072516-1, Exp. 07/04/2019; 082715-1, Exp. 06/24/2018;	CGMP Deviations: Lack of stability data and controls to support the manufacturer’s assigned retest or expiration date in firm's container/closure system.	American Pharmaceutical Ingredients LLC
Drugs	Diphenhydramine HCl USP f (or prescription compounding , packaged in a) 25g (NDC 58597-8081-4); b) 100g (NDC 58597-8081-6), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327	Class II	Lot #: a) 031715-1, Exp. 12/31/2019; b) 031715-1, Exp. 12/31/2019	CGMP Deviations: Lack of stability data and controls to support the manufacturer’s assigned retest or expiration date in firm's container/closure system.	American Pharmaceutical Ingredients LLC

Product Type	Product Description	Class	Code Info	Reason for Recall	Recalling Firm
Drugs	Doxycycline Hyclate USP for prescription compounding, packaged in a) 25g (NDC 58597-8082-4); b) 100g (NDC 58597-8082-6); c) 500g (NDC 58597-8082-7); d) 1000g (NDC 58597-8082-8), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327	Class II	Lot #: a) 082815-1, Exp. 06/04/2019; b) 082417-1, Exp. 03/04/2020; 082815-1, Exp. 06/04/2019; c) 082815-1, Exp. 06/04/2019; d) 082815-1, Exp. 06/04/2019	CGMP Deviations: Lack of stability data and controls to support the manufacturer's assigned retest or expiration date in firm's container/closure system.	American Pharmaceutical Ingredients LLC
Drugs	Duloxetine HCl USP for prescription compounding, packaged in a)100g (NDC 58597-8632-6); b)1000 g (NDC 58597-8632-8), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327	Class II	Lot #: a) 061115-2, Exp. 05/31/2019; b) 061115-1, Exp. 5/31/2019;	CGMP Deviations: Lack of stability data and controls to support the manufacturer's assigned retest or expiration date in firm's container/closure system.	American Pharmaceutical Ingredients LLC

Product Type	Product Description	Class	Code Info	Reason for Recall	Recalling Firm
Drugs	Estradiol USP (Micronized) (Yam) for prescription compounding, packaged in a) 1g (NDC 58597-8047-1); b) 5g (NDC 58597-8047-3); c) 10g (NDC 58597-8047-4); d) 25g (NDC 58597-8047-5); e) 100 g (NDC 58597-8047-6), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327	Class II	Lot #: a) 111516-1, Exp. 09/19/2018; b) 011917A-1, Exp. 09/22/2018; c) 111516-1, Exp. 09/19/2018; d) 011917A-1, Exp. 09/22/2018; 111516-1, Exp. 09/19/2018; e) 011917A-1, Exp. 09/22/2018; 111516-1, Exp. 09/19/2018	CGMP Deviations: Lack of stability data and controls to support the manufacturer's assigned retest or expiration date in firm's container/closure system.	American Pharmaceutical Ingredients LLC
Drugs	Estradiol Hemihydrate USP (Micronized) (Soy) for prescription compounding, packaged in a) 5g (NDC 58597-8001-3); b) 25g (NDC 58597-8001-5); c) 100 g (NDC 58597-8001-6), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327	Class II	Lot #: a) 083017-1, Exp. 7/22/2022; b) 083017-1, Exp. 7/22/2022; c) 083017-1, Exp. 7/22/2022.	CGMP Deviations: Lack of stability data and controls to support the manufacturer's assigned retest or expiration date in firm's container/closure system.	American Pharmaceutical Ingredients LLC

Product Type	Product Description	Class	Code Info	Reason for Recall	Recalling Firm
Drugs	<p>Estriol USP (Micronized) (Yam) for prescription compounding, packaged in a) 5g (NDC 58597-8048-2), b) 25g (NDC 58597-8048-4), c) 100g (NDC 58597-8048-6), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327.</p>	Class II	<p>Lot #: a) 111516-1, Exp. 9/19/2018; 011817-1, Exp. 9/10/2018; 111616-1, Exp. 5/18/2018; 052317A-1, Exp. 5/27/2019; b) 011817-1, Exp. 9/10/2018; 111616-1, Exp. 5/18/2018; 052317A-1, Exp. 5/27/2019; c) 011817-1, Exp. 9/10/2018; 052317A-1, Exp. 5/27/2019; 111616-1, Exp. 5/18/2018;</p>	<p>CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.</p>	American Pharmaceutical Ingredients LLC
Drugs	<p>Strone USP for prescription compounding, packaged in a) 5 g (NDC 58597-8049-3); b) 100mg (NDC 58597-8049-1); c) 25 g (NDC 58597-8049-4), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327</p>	Class II	<p>Lot #: a) 052915-2, Exp. 05/05/2017; b) 052915-2, Exp. 05/05/2017; c) 052915-1, Exp. 05/05/2017.</p>	<p>CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.</p>	American Pharmaceutical Ingredients LLC

Product Type	Product Description	Class	Code Info	Reason for Recall	Recalling Firm
Drugs	Fluconazole USP for prescription compounding, packaged in a) 25g (NDC 58597-8268-4); b) 100g (NDC 58597-8268-6); c)1000g (NDC 58597-8268-8) RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327	Class II	Lot #: a) 051115-1, Exp. 4/30/2020; 081017-1, expr 11/30/2021; 122216-1,122216-2, Exp. 12/31/2020; b) 041017-1, Exp. 11/30/2021; 051115-1, Exp. 4/30/2020; 081017-1, expr 11/30/2021; c) 041017-1, 041017-2, Exp. 11/30/2021; 122216-1, 122216-2, exp. 12/31/2020	CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.	American Pharmaceutical Ingredients LLC
Drugs	Flurbiprofen USP for prescription compounding, packaged in a) 25g (NDC 58597-8075-4); b)100g (NDC 58597-8075-6) ; c) 500g (NDC 58597-8075-7); d) 1000g (NDC 58597-8075-8), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327	Class II	Lot #: a) 062915-2, Exp. 04/30/2020; b) 022416-1, Exp. 11/30/2020; 062915-2, exp. 04/30/2020; 081215-2, Exp. 06/30/2020; c) 022416-1, Exp. 11/30/2020; 062915-1, Exp. 04/30/2020; 081215-1, Exp. 06/30/2020; d) 022416-1, Exp. 11/30/2020; 062915-1, Exp. 04/30/2020; 081215-1, Exp. 06/30/2020; 110415-1, Exp. 09/30/20120	CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.	American Pharmaceutical Ingredients LLC

Product Type	Product Description	Class	Code Info	Reason for Recall	Recalling Firm
Drugs	Gabapentin USP for prescription compounding, packaged in a) 25g (NDC 58597-8014-4); b) 100g (NDC 58597-8014-6); c) 500g (NDC 58597-8014-7); d) 1000g (NDC 58597-8014-8), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327	Class II	Lot #: a) 031116-7, exp. 03/31/2019; 112816-1, Exp. 03/01/2020 b) 011717-2, 051617-1, Exp. 04/30/2020; 031116-1, 031116-2, 031116-7, exp. 03/31/2019; 051215-1, exp. 03/05/2018; 063015-1, Exp. 05/19/2018; 092315-1, Exp. 07/17/2018; 111615-6, Exp. 08/27/2018; 112816-1, Exp. 03/01/2020; c) 011717-7, 011717-2, 051617-1, 082117B-1, Exp. 04/30/2020; ; 031116-2, 031116-4, 031116-5, 031116-7, Exp.. 03/31/2019; 051215-1, Exp. 03/05/2018; 092315-2, Exp. 07/17/2018; 111615-4, 111615-5, Exp. 08/27/2018; 112816-1, 112816-2, Exp. 03/01/2020; d) 011717-7, 051617-1, 082117B-1, Exp.	CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.	American Pharmaceutical Ingredients LLC

Product Type	Product Description	Class	Code Info	Reason for Recall	Recalling Firm
			04/30/2020; 031116-1, 031116-2, 031116-3, 031116-4, 031116-6, 031116-7, Exp. 03/31/2019; 051215-1, 051215-3, Exp. 03/05/2018; 063015-2, Exp. 05/19/2018; 111615-1, 111615-2, 111615-3, Exp. 08/27/2018; 112816-2, Exp. 03/01/2020		
Drugs	Hydroxyprogesterone Caproate USP for prescription compounding, packaged in a) 25g (NDC 58597-8051-4); b) 100g (NDC 58597-8051-6); c) 500g (NDC 58597-8051-7), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327	Class II	Lot #: a) 081015-1, Exp 07/23/2018; b) 081015-1, Exp 07/23/2018; 111116-1, Exp. 10/05/2019; c) 081015-1, Exp. 07/23/2018; 111116-1, Exp. 10/05/2019	CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.	American Pharmaceutical Ingredients LLC

Product Type	Product Description	Class	Code Info	Reason for Recall	Recalling Firm
Drugs	Imiquimod USP for prescription compounding, packaged in a) 1g (NDC 58597-8317-1); b) 10g (NDC 58597-8317-3); c) 25g (NDC 58597-8317-4) RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327	Class II	Lot #: a) 012016-2, Exp. 11/30/2020; b) 012016-1, Exp. 11/30/2020; c) 012016-1, Exp. 11/30/2020; 012016-2, Exp.11/30/2020;	CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.	American Pharmaceutical Ingredients LLC
Drugs	Itraconazole USP (Micronized) for prescription compounding, packaged in a) 10g (NDC 58597-8133-3); b) 25g (NDC 58597-8133-4); c)100g (NDC 58597-8133-6); d) 1000g (NDC 58597-8133-8), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327	Class II	Lot #: a) 061515-1, Exp. 04/30/2020; b) 080316-1, Exp. 06/30/2021; 052317C-1, Exp 02/28/2022; 061515-1, Exp. 04/30/2020; c) 061515-1, Exp. 04/30/2020; 080316-1, Exp. 06/30/2021; 091216-1, Exp. 07/31/2021; d) 061515-1, 061515-2, exp. 04/30/2020; 080316-1, Exp. 06/30/2021; 091216-1, Exp. 07/31/2021	CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.	American Pharmaceutical Ingredients LLC

Product Type	Product Description	Class	Code Info	Reason for Recall	Recalling Firm
Drugs	Ketamine HCl USP for prescription compounding, packaged in a) 25g (NDC 58597-8333-4); b) 100g (NDC 58597-8333-6); c) 500g (NDC 58597-8333-7); d) 1000g (NDC 58597-8333-8), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327	Class II	Lot #: a) 102015-3, Exp. 07/31/2020; 081616-3R, Exp. 02/28/2021; b) 081616-3, 081616-3R, Exp. 02/28/2021; 102015-2, Exp. 07/31/2020; c) 081616-1R, Exp. 02/28/2021; 081616-1, Exp. 02/29/2021; 102015-1, 102015-2, Exp. 07/31/2020; d) 102015-1, Exp. 07/31/2020; 081616-1, Exp. 02/29/2021; 081616-1R, 081616-2R, Exp. 02/28/2021.	CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.	American Pharmaceutical Ingredients LLC
Drugs	Ketoconazole USP for prescription compounding, packaged in a) 25g (NDC 58597-8053-4); b) 100g (NDC 58597-8053-6); c) 500g (NDC 58597-8053-7) RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327	Class II	Lot #: a) 091115-1, Exp. 07/31/2020; 091115-2, Exp. 07/31/2020; b) 091115-1, Exp. 07/31/2020; c) 091115-1, Exp. 07/31/2020.	CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.	American Pharmaceutical Ingredients LLC

Product Type	Product Description	Class	Code Info	Reason for Recall	Recalling Firm
Drugs	Ketoprofen USP (Micronized) for prescription compounding, packaged in a) 25g (NDC 58597-8336-4); b) 100g (NDC 58597-8336-6); c) 500g (NDC 58597-8336-7); d) 1000g (NDC 58597-8336-8), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327	Class II	Lot #: a) 051916-1, Exp. 04/30/2019; 061015-1, Exp. 03/03/2018; 041216-2, Exp. 03/27/2019; b) 051916-1, Exp. 04/30/2019; 052517-1, Exp. 02/28/2022; 061015-1, Exp. 03/03/2018; c) 041216-1, Exp. 03/27/2019; 051916-3, Exp. 04/30/2019; 052517-1, Exp. 02/28/2022; 061015-1, Exp. 03/03/2018; d) 041216-1, 041216-3, Exp. 03/27/2019; 051916-2, 051916-3, 051916-4, Exp. 04/30/2019; 061015-1, Exp. 03/03/2018;	CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.	American Pharmaceutical Ingredients LLC

Product Type	Product Description	Class	Code Info	Reason for Recall	Recalling Firm
Drugs	Leucovorin Calcium USP for prescription compounding, packaged a) 100mg, (NDC 58597-8084-1); b) 1g (NDC 58597-8084-3); c) 5g (NDC 58597-8084-4); d) 25 g (NDC 58597-8084-5), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327	Class II	Lot #: a) 092415-1, Exp. 05/21/2018; b) 092415-1, Exp. 05/21/2018; 122915-1, Exp. 05/15/2018; c) 092415-1, Exp. 05/21/2018; 122915-1, Exp. 05/15/2018 d) 092415-1, Exp. 05/21/2018;	CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.	American Pharmaceutical Ingredients LLC
Drugs	Levetiracetam USP for prescription compounding, packaged in a) 500g (NDC 58597-8353-7); b) 1000g (NDC 58597-8353-8), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327	Class II	Lot #: a) 072616-1, Exp. 06/29/2019; b) 060115-1, Exp. 01/23/2018; 072616-1, Exp. 06/29/2019;	CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.	American Pharmaceutical Ingredients LLC

Product Type	Product Description	Class	Code Info	Reason for Recall	Recalling Firm
Drugs	Levocetirizine Dihydrochloride for prescription compounding, packaged in a) 25g (NDC 58597-8355-6); b) 100g (NDC 58597-8355-6), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327	Class II	Lot #: a) 073115-1, Exp. 6/30/2020; b) 073115-1, Exp. 6/30/2020;	CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.	American Pharmaceutical Ingredients LLC
Drugs	Levofloxacin Hemihydrate USP for prescription compounding, packaged in a) 100g (NDC 58597-8085-6); b) 1000g (NDC 58597-8085-8), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327	Class II	Lot #: a) 072915-1, Exp. 07/05/2019; b) 072915-1, Exp. 07/05/2019	CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.	American Pharmaceutical Ingredients LLC
Drugs	Levothyroxine Sodium USP for prescription compounding, packaged in a) 1g (NDC 58597-8638-1); b) 5 g (NDC 58597-8638-2), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327	Class II	Lot #: a) 090517B-2, Exp. 11/17/2019; b) 090517B-2, Exp. 11/17/2019	CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.	American Pharmaceutical Ingredients LLC

Product Type	Product Description	Class	Code Info	Reason for Recall	Recalling Firm
Drugs	Lidocaine HCl USP for prescription compounding, packaged in a) 100g (NDC 58597-8020-6); b) 500g (NDC 58597-8020-7); c) 1000g (NDC 58597-8020-8) RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327	Class II	Lot #: a) 021115-1, Exp. 01/15/2020; 080415-1, Exp. 03/22/2020; b) 020116-2, Exp. 12/13/2020; 021115-1, Exp. 01/15/2020; 080415-1, Exp. 03/22/2020; c) 020116-1, 020116-2, Exp. 12/13/2020; 021115-1, exp. 01/15/2020; 080415-1, Exp. 03/22/2020; 082416-1, 082416-2 Exp. 01/31/2021.	CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.	American Pharmaceutical Ingredients LLC
Drugs	Lidocaine USP for prescription compounding, packaged in a) 25g (NDC 58597-8019-4); b) 100g (NDC 58597-8019-6); c) 500g (NDC 58597-8019-7); d) 1000 (NDC 58597-8019-8), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327	Class II	Lots #: a) 110215-2, Exp. 09/30/2020; b) 110215-1, Exp. 09/30/2020; 082516-1, Exp. 05/31/2021; c) 110215-1, Exp. 09/30/2020; 082516-1, Exp. 05/31/2021; d) 110215-1, Exp. 09/30/2020; 082516-1, Exp. 05/31/2021.	CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.	American Pharmaceutical Ingredients LLC

Product Type	Product Description	Class	Code Info	Reason for Recall	Recalling Firm
Drugs	Lincomycin HCl USP for prescription compounding, packaged in a)100g (NDC 58597-8359-6); b) 500g (NDC 58597-8359-7); c) 1000g (NDC 58597-8359-8), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327	Class II	Lot #: a) 110515-2, Exp. 09/30/2018; b) 110515-1, Exp. 09/30/2018; c) 110515-1, Exp. 09/30/2018.	CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.	American Pharmaceutical Ingredients LLC
Drugs	Liothyronine Sodium USP for prescription compounding ,1g, RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327, NDC 58597-8021-2.	Class II	Lot #: 090517A-1, Exp. 09/13/2018	CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.	American Pharmaceutical Ingredients LLC
Drugs	Medroxyprogesterone Acetate USP (Micronized) for prescription compounding 1000 g, RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327, NDC 58597-8055-8	Class II	Lot #: 081415-2, Exp. 05/03/2018	CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.	American Pharmaceutical Ingredients LLC

Product Type	Product Description	Class	Code Info	Reason for Recall	Recalling Firm
Drugs	Naltrexone HCl USP (Dihydrate) for prescription compounding, packaged in a) 1g (NDC 58597-8407-1); b) 5g (NDC 58597-8407-2); c) 25g (NDC 58597-8407-4); d) 100g (NDC 58597-8407-6), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327	Class II	Lot #: a) 120916-1, Exp. 10/31/2019; b) 120916-1, Exp. 10/31/2019 c) 120916-1, Exp. 10/31/2019; d) 120916-1, Exp. 10/31/2019.	CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.	American Pharmaceutical Ingredients LLC
Drugs	Nandrolone Decanoate USP for prescription compounding, packaged in a) 25g (NDC 58597-0081-4); b) 100g (NDC 58597-0081-6); c) 500g (NDC 58597-0081-7); d) 1000g (NDC 58597-0081-8), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327	Class II	Lot #: a) 012716-1, 012716-2, Exp. 01/12/2019; 110316-3, Exp. 09/21/2021 b) 012716-1, 012716-3, Exp. 01/12/2019; 110316-1, 110316-3, Exp. 09/21/2021; c) 012716-1, 012716-3, Exp. 01/12/2019; 110316-1, 110316-2, Exp. 09/21/2021; exp. 09/21/2021; d) 012716-1, 012716-3, Exp. 01/12/2019; 041717-2, Exp. 04/06/2022; 110316-1, 110316-2, Exp. 09/21/2021.	CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.	American Pharmaceutical Ingredients LLC

Product Type	Product Description	Class	Code Info	Reason for Recall	Recalling Firm
Drugs	Nifedipine USP for prescription compounding, packaged in a) 5g (NDC 58597-8025-2); b) 25g (NDC 58597-8025-4); c) 100g (NDC 58597-8025-6); d) 500g (NDC 58597-8025-7), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327	Class II	Lot #: a) 020615-2, Exp. 12/04/2018; b) 020615-2, Exp. 12/04/2018; c) 020615-1, Exp. 12/04/2018; d) 020615-1, Exp. 12/04/2018; 020615-2, Exp. 12/04/2018.	CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.	American Pharmaceutical Ingredients LLC
Drugs	Oxandrolone USP for prescription compounding, packaged in a) 25g (NDC 58597-0082-4); b) 100g (NDC 58597-0082-6); c) 500g (NDC 58597-0082-7), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327	Class II	Lot #: a) 012616-2, Exp. 01/08/2019; b) 012616-1, Exp. 01/08/2019; 012616-2, Exp. 01/08/2019; c) 012616-1, Exp. 01/08/2019; 012616-3, Exp. 01/08/2019.	CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.	American Pharmaceutical Ingredients LLC
Drugs	Pentoxifylline USP for prescription compounding, packaged in a) 25g (NDC 58597-8429-4); b) 100g (NDC 58597-8429-6), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327	Class II	Lot #: a) 092515-1, Exp. 5/31/2020; b) 092515-1, Exp. 5/31/2020.	CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.	American Pharmaceutical Ingredients LLC

Product Type	Product Description	Class	Code Info	Reason for Recall	Recalling Firm
Drugs	Phentolamine Mesylate USP for prescription compounding, packaged in a) 1g (NDC 58597-8077-3); b) 5g (NDC 58597-8077-4); c) 500g (NDC 58597-8077-7), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327	Class II	Lot #: a) 080315-1, Exp. 04/05/2018; b) 080315-1, Exp. 04/05/2018, c) 080315-1, Exp. 04/05/2018.	CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.	American Pharmaceutical Ingredients LLC
Drugs	Prilocaine HCl USP for prescription compounding, packaged in a) 100g (NDC 58597-8028-6); b) 500g (NDC 58597-8028-7); c) 1000g (NDC 58597-8028-8), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327	Class II	Lot #: a) 071117-1, Exp. 06/16/2020; b) 071117-1, Exp. 06/16/2020; c) 071117-1, Exp. 06/16/2020	CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.	American Pharmaceutical Ingredients LLC

Product Type	Product Description	Class	Code Info	Reason for Recall	Recalling Firm
Drugs	Progesterone USP (Micronized) (Yam) for prescription compounding, packaged in a) 1g (NDC 58597-8471-1); b) 10g (NDC 58597-8471-3); c) 25g (NDC 58597-8471-4); d) 100g (NDC 58597-8471-6); e) 500g (NDC 58597-8471-7); f) 1000g (NDC 58597-8471-8); g) 5000g (NDC 58597-8471-9), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327	Class II	Lot #: a) 031115-3, Exp. 12/24/2019; b) 031115-3, Exp. 12/24/2019 c) 031115-3, Exp. 12/24/2019; 050815-3, Exp. 04/14/2020; d) 010716-1, 010716-6, Exp. 11/10/2018; 030116-4, Exp. 12/04/2018; 031115-2, Exp. 12/24/2019; 060116-9, Exp. 4/28/2019; 080416-1, 080416-4, Exp. 06/05/2019; 080615-4, Exp. 07/29/2020; 112015-6, Exp. 10/7/2018; 121916-7, Exp. 11/10/2018; e) 080615-5, Exp. 07/29/2020; 010716-4, 010716-5, Exp. 11/10/2018; 030116-2, Exp. 12/04/2018; 031115-5, Exp. 12/24/2019; 060116-1, 060116-4, 060116-5, Exp. 04/28/2019; 080416-1, 080416-2, exp. 06/05/2019; 112015-1, Exp. 10/07/2018; 121916-2, 121916-3,	CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.	American Pharmaceutical Ingredients LLC

Product Type	Product Description	Class	Code Info	Reason for Recall	Recalling Firm
			121916-6, Exp. 11/02/2019; f) 112015-5, Exp. 10/07/2018; 010716-1, Exp. 11/10/2018; 030116-3, Exp. 12/04/2018; 010716-1, 010716-2, 010716-3, 010716-8, Exp. 11/10/2018; 030116-1, 030116-3, 030116-4,030116-5, Exp. 12/4/2018; 031115-5, Exp. 12/24/2019; 060116-4, 060116-6, 060116-8, 060116-9, Exp. 04/28/2019; 080416-3, 080416-4, 080416-5, Exp. 06/05/2019; 112015-2, 112015-3, 112015-4,112015-6, 112015-7, Exp. 10/07/2018; 121916-1, Exp. 11/02/2019; 121916-3, 121916-4, 121916-5, 121916-7 121916-8, Exp.11/02/2019; g) 060116-2, 060116-3 060116-7, Exp.		

Product Type	Product Description	Class	Code Info	Reason for Recall	Recalling Firm
			04/28/2019.		

Product Type	Product Description	Class	Code Info	Reason for Recall	Recalling Firm
Drugs	Sildenafil Citrate USP for prescription compounding, packaged in a) 5g (NDC 58597-8088-2);b) 25g (NDC 58597-8088-4); c) 50g (NDC 58597-8088-5); d) 100g (NDC 58597-8088-6); e) 500g (NDC 58597-8088-7); f)1000g (NDC 58597-8088-8), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327	Class II	Lot #: a) 021317-4, Exp. 12/31/2021; b) 021317-2R, 021317-4, Exp. 12/31/2021; 050115-4, Exp. 3/31/2020; 101915-5, Exp. 08/31/2020 c) 050115-3, 050115-4, Exp. 03/31/2020; d) 021317-3R, Exp. 12/31/2021; 050115-2, 050115-3, Exp. 03/31/2020; 101915-3, 101915-4,101915-5, Exp. 08/31/2020; e) 021317-2R, Exp. 12/31/2021; 050115-2, exp. 03/31/2020; 101915-1, 101915-2,101915-5, Exp. 08/31/2020; f) 021317-1R, 021317-2R,021317-3R, Exp. 12/31/2021; 050115-1, 050115-2, Exp. 03/31/2020; 101915-1, 101915-2, Exp. 08/31/2020.	CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.	American Pharmaceutical Ingredients LLC

Product Type	Product Description	Class	Code Info	Reason for Recall	Recalling Firm
Drugs	Stanozolol USP for prescription compounding, packaged in a) 25g (NDC 58597-8525-3); b) 100g (NDC 58597-8525-6); c) 500g (NDC 58597-8525-7); d) 1000g (NDC 58597-8525-8), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327	Class II	Lot #: a) 080616-1, 4/26/2019; b) 080616-1, 4/26/2019; c) 080616-1, 4/26/2019; d) 080616-1, 4/26/2019.	CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.	American Pharmaceutical Ingredients LLC
Drugs	Sumatriptan Succinate USP for prescription compounding, 25g, RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327, NDC 58597-8633-4.	Class II	Lot #: 061615-1, Exp. 12/31/2019	CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.	American Pharmaceutical Ingredients LLC
Drugs	Sumatriptan USP for prescription compounding, packaged in 10g (NDC 58597-8089-3); b) 25g (NDC 58597-8089-4); c) 100g (NDC 58597-8089-6), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327	Class II	Lot #: a) SUT1213030SP-11192014, Exp. 11/30/2018; b) SUT1213030SP-11192014, exp. 11/30/2018; c) SUT1213030SP-7222015, Exp. 11/30/2018.	CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.	American Pharmaceutical Ingredients LLC

Product Type	Product Description	Class	Code Info	Reason for Recall	Recalling Firm
Drugs	Tacrolimus USP (Monohydrate) for prescription compounding, packaged in a) 1g (NDC 58597-8029-4); b) 5g (NDC 58597-8029-5), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327	Class II	Lot #: a) 053116-1R, Exp.04/30/2018; b) 053116-1R, Exp.04/30/2018	CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.	American Pharmaceutical Ingredients LLC

Product Type	Product Description	Class	Code Info	Reason for Recall	Recalling Firm
Drugs	Tadalafil USP (Monohydrate) for prescription compounding, packaged in a) 5g (NDC 58597-8538-2); b) 25g (NDC 58597-8538-4); c)100g (NDC 58597-8538-6); d) 500g (NDC 58597-8538-7); d) 1000g (NDC 58597-8538-8), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327	Class II	Lot #: a) 020717-3, Exp. 12/31/2021; b) 020717-2 020717-4, 020717-5 Exp. 12/31/2021; 092816-2, 092816-3, Exp. 07/31/2021; 121015-4, 121015-5, 121015-6, Exp.10/31/2020; c) 020717-1, 020717-4, 020717-5, Exp. 12/31/2021; 092816-1, Exp. 07/31/2021; 092816-2, Exp. 07/31/2021; 121015-1,121015-3, Exp. 10/31/2020; d) 020717-1, 020717-2, Exp. 12/31/2021; 092816-1, Exp. 07/31/2021; 121015-2, Exp. 10/31/2020; e) 020717-1,020717-2 Exp. 12/31/2021.	CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.	American Pharmaceutical Ingredients LLC

Product Type	Product Description	Class	Code Info	Reason for Recall	Recalling Firm
Drugs	Testosterone (Soy) (Micronized) USP for prescription compounding, packaged in a) 25g (NDC 58597-0077-4); b) 100g (NDC 58597-0077-6), c) 500g (NDC 58597-0077-7); d)1000g (NDC 58597-0077-8), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327	Class II	Lot #: a) 071516-3, Exp. 04/01/2019; b) 071516-3, Exp. 4/1/2019; c) 071516-1, 071516-2, Exp. 04/01/2019; d) 071516-1, 071516-3, Exp. 04/01/2019, 032117B-1, Exp. 2/9/2020.	CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.	American Pharmaceutical Ingredients LLC
Drugs	Testosterone Cypionate USP (Micronized) for prescription compounding, packaged in a)100g (NDC 58597-0078-6); b) 500g (NDC 58597-0078-7); c) 1000g (NDC 58597-0078-8), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327	Class II	Lot #: a) 032117A-6, Exp. 01/21/2019; 112916-2, 112916-4, Exp. 10/17/2018; b) 032117A-4, 032117A-5, Exp. 01/21/2019; 112916-1, Exp. 10/17/2018; 112916-4, Exp. 10/17/2018; c) 032117A-1, 032117A-2, 032117A-3, 032117A-4, 032117A-5, Exp. 01/21/2019; 112916-1, 112916-2, 112916-3, 112916-4, Exp. 10/17/2018.	CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.	American Pharmaceutical Ingredients LLC

Product Type	Product Description	Class	Code Info	Reason for Recall	Recalling Firm
Drugs	Testosterone Enanthate USP for prescription compounding, packaged in a) 25g (NDC 58597-0079-4); b) 100g (NDC 58597-0079-6); c) 500g (NDC 58597-0079-7); d) 1000g (NDC 58597-0079-8), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327	Class II	Lot #: a) 042016-2, Exp. 4/6/2019; b) 041217-1, Exp. 02/09/2019; 042016-2, 042016-3, Exp. 4/6/2019; c) 041217-1, 041217-3, Exp. 02/09/2019; 042016-1, Exp. 04/06/2019; 042016-2, Exp. 4/6/2019; d) 041217-3, Exp. 01/09/2019; 042016-1, Exp. 4/6/2019.	CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.	American Pharmaceutical Ingredients LLC

Product Type	Product Description	Class	Code Info	Reason for Recall	Recalling Firm
Drugs	Testosterone USP (Micronized) (Yam) for prescription compounding, packaged in a) 25g (NDC 58597-8546-4); b) 100g (NDC 58597-8546-6); c) 500g (NDC 58597-8546-7); d) 1000g (NDC 58597-8546-8), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327	Class II	Lot #: a) b) 032117C-1, Exp. 02/11/2020; 070716-2, Exp. 03/22/2019; 121616-1, Exp. 08/20/2019; 071516-3, Exp. 4/1/2019; c) 032117C-1, Exp. 02/11/2020; 070716-1, Exp. 03/22/2019; 070716-2, Exp. 03/22/2019; 121616-1, Exp. 08/20/2019 d) 032117C-1, Exp. 02/11/2020; 061317-1, Exp. 4/30/2020; 061617-1, Exp. 05/01/2020; 070716-1, 070716-2, Exp. 03/22/2019; 121616-1, Exp. 8/20/2019.	CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.	American Pharmaceutical Ingredients LLC

Product Type	Product Description	Class	Code Info	Reason for Recall	Recalling Firm
Drugs	Tramadol HCl USP (CIV) for prescription compounding, packaged in a) 25g (NDC 58597-8032-4); b) 100g (NDC 58597-8032-6); c) 500g (NDC 58597-8032-7); d)1000g (NDC 58597-8032-8), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327	Class II	Lot #: a) UT2140602-1132014, Exp. 05/31/2019; b) UT2140602-1142014, UT2140602-4222015, Exp. 05/31/2019; UT2140602-10292014, Exp. 05/31/02019; UT2131205UI-1192015, Exp.11/30/2018; UT2140602-10292014, Exp. 05/31/2019; c) UT2140602-10282014, Exp. 05/31/2019; UT2131205UI, Exp. 11/30/2018; UT2140602-4222015, Exp. 5/31/2019; d) UT2140602-10282014, Exp. 05/31/2019; UT2131205UI, UT2131205UI-1192015, Exp. 11/30/2018.	CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.	American Pharmaceutical Ingredients LLC

Product Type	Product Description	Class	Code Info	Reason for Recall	Recalling Firm
Drugs	Tretinoin USP for prescription compounding, packaged in a) 5g (NDC 58597-8033-2); 1b) 10g (NDC 58597-8033-3); c) 25g (NDC 58597-8033-4), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327	Class II	Lot #: a) 062615-1, Exp. 06/09/2018; 071816-1, exp. 06/05/2019; b) 043015-1, Exp. 04/01/2018; 062615-1, Exp. 06/09/2018; 071816-1, exp. 06/05/2019; c) 062615-1, Exp. 06/09/2018; 071816-1, Exp. 06/05/2019.	CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.	American Pharmaceutical Ingredients LLC
Drugs	Ursodiol USP for prescription compounding, packaged in a) 100g (NDC 58597-8038-6); b) 500g (NDC 58597-8038-7), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327	Class II	Lot #: a) 071316-1, Exp. 05/27/2019; b) 071316-1, Exp. 05/27/2019	CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.	American Pharmaceutical Ingredients LLC
Drugs	Vancomycin HCl USP for prescription compounding, packaged in a) 25g (NDC 58597-8091-4); b) 100g (NDC 58597-8091-6); c) 500g (NDC 58597-8091-7), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327	Class II	Lot #: a) 013117-1, Exp. 06/30/2019; b) 013117-1, Exp. 06/30/2019; c) 013117-1, Exp. 06/30/2019.	CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.	American Pharmaceutical Ingredients LLC

Product Type	Product Description	Class	Code Info	Reason for Recall	Recalling Firm
Drugs	Vardenafil HCl USP (trihydrate) for prescription compounding, packaged in a) 5g (NDC 58597-8575-2); b) 100g (NDC 58597-8575-6); c) 500g (NDC 58597-8575-7); d) 1000g (NDC 58597-8575-8), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327	Class II	Lot #: a) 070717-2, Exp. 05/31/2020; b) 070717-1, Exp. 05/31/2020; c) 070717-1, Exp. 05/31/2020; d) 070717-1, Exp. 05/31/2020.	CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.	American Pharmaceutical Ingredients LLC
Drugs	Verapamil HCl USP for prescription compounding, packaged in a) 100g (NDC 58597-8039-6); b) 500g (NDC 58597-8039-7); c) 1000g (NDC 58597-8039-8), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327	Class II	Lot #: a) 072216-1, Exp. 11/26/2019; b) 072216-1, Exp. 11/26/2019; c) 072216-1, Exp. 11/26/2019;	CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.	American Pharmaceutical Ingredients LLC

Product Type	Product Description	Class	Code Info	Reason for Recall	Recalling Firm
Drugs	Ascorbic Acid USP, for prescription compounding, packaged in a) 100g (NDC 58597-8120-6); b) 500g (NDC 58597-8120-7); c) 1000g (NDC 58597-8120-8); d) 5000g (NDC 58597-8120-9); e) 25000g (NDC 58597-8120-3), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327	Class II	Lot #: b) 030816-1, Exp. 05/20/2018; c) 030816-1, Exp. 05/20/2018; d) 030816-3, Exp. 05/20/2018; e) 030816-2, Exp. 05/20/2018;	CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.	American Pharmaceutical Ingredients LLC
Drugs	Biotin USP (Vitamin H) for prescription compounding, packaged in a) 500mg (NDC 58597-8142-1); b) 1g (NDC 58597-8142-2); c) 5g (NDC 58597-8142-3); d) 25g (NDC 58597-8142-4), Rx only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327	Class II	Lot #: a) 070815-2, Exp. 04/24/2018; b) 070815-2, Exp. 04/24/2018; c) 070815-2, Exp. 04/24/2018; 110416-2, Exp. 06/30/2019; d) 110416-1, Exp. 06/30/2019; 070815-1, Exp. 04/24/2018.	CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.	American Pharmaceutical Ingredients LLC

Product Type	Product Description	Class	Code Info	Reason for Recall	Recalling Firm
Drugs	Methylcobalamin (Vitamin B12) for prescription compounding, packaged in a) 500mg (NDC 58597-8142-1); b) 1g (NDC 58597-8056-2); c) 5g (NDC 58597-8056-3); d) 10g (NDC 58597-8056-4), e) 25 g (NDC 58597-8056-4); f) 100g (NDC 58597-8056-6), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327	Class II	Lot #: a) b) 012216-1, Exp. 12/31/2019; 051515-3, Exp. 02/28/2019; 051515-3, Exp. 02/28/2019; c) 012216-1, Exp. 12/31/2019; 051515-3, Exp. 02/28/2019 d) 012216-1, Exp. 12/31/2019; 051515-2, Exp. 02/28/2019; 061516-1, Exp. 01/31/2020; e) 051515-2, exp. 02/28/2019; 061516-1, Exp. 01/31/2020; ; 082117A-1, Exp. 05/31/2021; f) 012216-1, Exp. 12/31/2019; 051515-1, Exp. 02/28/2019; 061516-1, Exp. 01/31/2020; ; 082117A-1, Exp. 05/31/2021	CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.	American Pharmaceutical Ingredients LLC

Product Type	Product Description	Class	Code Info	Reason for Recall	Recalling Firm
Drugs	Cyanocobalamin USP (Vitamin B12) for prescription compounding, packaged in a) 1g (NDC 58597-8044-1), b) 5g (NDC 58597-8044-2), c) 25g (NDC 58597-8044-4), d) 100g (NDC 58597-8044-6), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327	Class II	Lot #: a) 031815-2, Exp. 1/14/2020; b) 031815-2, Exp. 1/14/2020; c) 031815-2, Exp. 1/14/2020; d) 031815-1, Exp. 1/14/2020	CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.	American Pharmaceutical Ingredients LLC
Drugs	Fluticasone propionate USP (Micronized) for prescription compounding, packaged in a) 1g (NDC 58597-8276-1), b) 10g (NDC 58597-8276-3), c) 25g (NDC 58597-8276-4), d) 100g (NDC 58597-8276-6), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327	Class II	Lot #: a) 052615-2, Exp. 4/30/2020; 020916-1, Exp. 12/31/2020; b) 092115-1, Exp. 8/31/2020; 092115-2, Exp. 8/31/2020; 020916-1, Exp. 12/31/2020; 110315-3, Exp. 9/30/2020; c) 020916-1, Exp. 12/31/2020, 110315-2, Exp. 9/30/2020; d) 020916-1, Exp. 12/31/2020	CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.	American Pharmaceutical Ingredients LLC

Product Type	Product Description	Class	Code Info	Reason for Recall	Recalling Firm
Drugs	INFeD (Iron Dextran Injection USP) 100 mg elemental iron/2 ml (50 mg/mL), Rx Only, packaged in a) single dose vials, (NDC 52544-931-07), b) carton of 10 x 2 ml Single Dose Vials (NDC 52544-931-02) Distributed by: Actavis Pharma, Inc. Parsippany, NJ 07054, Manufactured by: Patheon Italia S.p.A. Ferentino, Italy 03013.	Class II	Lot# 15W05A, Exp.FEB-2018; 16W02A, Exp. DEC 2018; 16W05A, Exp. JAN-2019; 16W13A, Exp. APR-2019; 16W15A, 16W16A, 16W17A, Exp. MAY 2019; 16W18A, Exp. JUN 2019; 16W20A, 16W22A, Exp. SEP 2019; 17W01A, 17W02A, Exp. DEC-2019; 17W04A, 17W05A, Exp. JAN 2020; 17W09A, Exp. MAR-2020; 17W11A, 17W13A, Exp. MAY 2020; 17W14A, 17W15A, Exp. JUN 2020	Failed Stability Specifications: Product stability testing results did not meet specifications for iron content.	ALLERGAN
Drugs	Acyclovir Tablets, USP, 400 mg, 50 Tablets (5 x 10) unit dose blisters [NDC 50268-061-11] per carton [NDC 50268-061-15], Rx Only, Manufactured for: AvKARE, Inc., Pulaski, TN 38478	Class II	Lot: 19900, expr 05/2019	Presence of Foreign Tablet/Capsule; cartons labeled to contain Acyclovir tablets may contain Torsemide tablets in some of the blister cavities.	Apace KY LLC

Product Type	Product Description	Class	Code Info	Reason for Recall	Recalling Firm
Drugs	SyrSpend SF Suspending Base, a) 500 mL (NDC 51552-1079-5) and b) 4 L (NDC 51552-1079-9), Rx Only, Manufactured by Fagron Inc. St. Paul, MN 55120	Class II	a) 17128-U80-039976, exp. 10/02/2020; b) 17128-U80-039977, exp. 10/02/2020	Microbial contamination of Non-Sterile Product; product contamination with yeast and mold (<i>Paecilomyces saturatus</i> and <i>Aspergillus fumigatus</i>).	Fagron, Inc
Drugs	PVP Scrub Solution, Povidone Iodine, 7.5% (equivalent to 0.75% available iodine), 4 FL OZ bottle, Manufactured in USA by Medline Industries, Inc., Northfield, IL 60093; Product Number MDS093945; NDC 53329-938-04	Class II	Lot #: 16EJ0023, Exp 04/18	Subpotent Drug: product not meeting the iodine assay level requirements through the labeled expiry.	Medline Industries Inc
Drugs	0.9% Sodium Chloride Irrigation USP, 1000 mL Plastic Irrigation Container (PIC), Rx only, B. Braun Medical Inc., Irvine, CA 92614, Catalog # R5200-01, NDC 0264-2201-00.	Class II	Batch # J7N912, Exp 10/31/20	Presence of Particulate Matter: Customer complaint of particulate matter which has been identified as polyethylene, which is consistent with the material used to manufacture the container cap was received.	B. Braun Medical Inc

Product Type	Product Description	Class	Code Info	Reason for Recall	Recalling Firm
Drugs	Labetalol Hydrochloride Injection, USP, 100 mg/ 20 mL (5 mg/mL), 20 mL Multidose Vial, Rx only, labeled as a) Hospira, Inc., Lake Forest, IL 60045, NDC 0409-2267-20; and b) NOVAPLUS, Manufactured by Hospira, Inc., Lake Forest, IL 60045, NDC 0409-2267-25.	Class II	Lots: a) 74370DD, Exp 1FEB2019; 75035DD, 75115DD, Exp 1MAR2019; b) 74230DD, Exp 1FEB2019	Defective Container: Cracked glass at the rim surface of glass vials, covered by the stopper and crimp seal.	Hospira Inc. A Pfizer Company
Drugs	Coppertone Kids Sunscreen Spray (avobenzone 3%, Homosalate 10%, Octisalate 5%, Octocrylene 4%, Oxybenzone 5%) 8.3 oz. bottle, Dist. by: Bayer Healthcare LLC Whippany, NJ 07981, UPC 41100573636.	Class II	Lot#: 7N04CS, 7N05CS, Exp. 11/2019	Labeling: Label mix-up	Bayer HealthCare Pharmaceuticals, Inc.
Drugs	Vardenafil HCl, USP (trihydrate), 500 GM Part # 330-05, Rx only, For Manufacturing, Repackaging and Processing for Rx and Research Only, Kalchem International, Inc. 224 South Main Street Lindsay, OK 73052 888-298-9905, NDC 60592-330-05	Class II	Lot #: 070717-1	cGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.	Kalchem International, Inc.

Product Type	Product Description	Class	Code Info	Reason for Recall	Recalling Firm
Drugs	Vancomycin 1g added to 250mL of 0.9% Sodium Chloride IV bag, Rx only, APOLLOcare, 3801 Mojave Ct., Suite 101, Columbia, MO 65202, NDC 71170-254-25.	Class II	Lot: AC-015558, Exp 03/07/2018	Stability Data Does Not Support Expiry: 90-day beyond use date (BUD) for the affected product is not supported.	Apollo Care
Drugs	Vancomycin 1.25g added to 250mL of 0.9% Sodium Chloride IV bag, Rx only, APOLLOcare, 3801 Mojave Ct., Suite 101, Columbia, MO 65202, NDC 71170-264-25.	Class II	Lot: AC-015560, Exp 03/14/2018	Stability Data Does Not Support Expiry: 90-day beyond use date (BUD) for the affected product is not supported.	Apollo Care
Drugs	Ibuprofen Tablets USP, 200 mg, 100-count bottles, OTC, Distributed By: Spirit Pharmaceuticals, LLC Ronkonkoma, NY 11779, NDC 68210-0800-1	Class II	Lot#: HJ6138	CGMP deviations: Ibuprofen is being recalled in response to previous recall	Spirit Pharmaceuticals, LLC
Drugs	Valganciclovir Tablets, USP, 450 mg, 60-count bottle, Rx Only, Manufactured for Camber Pharmaceuticals, Inc. Piscataway, NJ 08854, By: Hetero Hetero Labs Limit Unit V Pollypally Jadcherla Mahaboob Nagar - 509 301 India. NDC # 31722-832-60	Class II	Lot #s VGC17040 & VGC17041, EXP 07/2019	Temperature Abuse: Valganciclovir Tablets USP 450 mg and Valacyclovir Tablets USP 1 gram were exposed to higher temperature at airport or cargo and in the same consignment of Famciclovir complaint batch (D-0415-2018).	Hetero Labs Limited Unit V

Product Type	Product Description	Class	Code Info	Reason for Recall	Recalling Firm
Drugs	Valacyclovir Tablets USP 1 gram, 30-count bottle, Rx Only, Manufactured for Camber Pharmaceuticals, Inc. Piscataway, NJ 08854 By: Hetero Hetero Labs Limit Unit V Pollypally Jadcherla Mahaboob Nagar - 509 301 India NDC # 31722-705-30	Class II	Lot # VLC17027 Exp 07-2019	Temperature Abuse: Valganciclovir Tablets USP 450 mg and Valacyclovir Tablets USP 1 gram were exposed to higher temperature at airport or cargo and in the same consignment of Famciclovir complaint batch (D-0415-2018).	Hetero Labs Limited Unit V
Drugs	methylPREDNISolone Sodium Succinate for Injection, USP, 40 mg* per vial, Single-Dose Vial, Rx only, Mfd. for: Sagent Pharmaceuticals, Schaumburg, IL 60195 (USA), Made in India. NDC 25021-807-05.	Class II	Lot #: AJM601, Exp. Jul-2018; AJM701, AJM702, Exp. Dec-2018	Failed Impurities/Degradation Specifications: High out of specification results for an impurity.	Sagent Pharmaceuticals Inc
Drugs	methylPREDNISolone Sodium Succinate for Injection, USP, 125 mg* per vial, Single-Dose Vial, Rx only, Mfd. for: Sagent Pharmaceuticals, Schaumburg, IL 60195 (USA), Made in India. NDC 25021-808-10.	Class II	Lot #: AJN601, Exp. Jun-2018; AJN701, AJN702, Exp. Dec-2018	Failed Impurities/Degradation Specifications: High out of specification results for an impurity.	Sagent Pharmaceuticals Inc

Product Type	Product Description	Class	Code Info	Reason for Recall	Recalling Firm
Drugs	methylPREDNISolone Sodium Succinate for Injection, USP, 1 gram* per vial, Single-Dose Vial, Rx only, Mfd. for: Sagent Pharmaceuticals, Schaumburg, IL 60195 (USA), Made in India. NDC 25021-810-30.	Class II	Lot #: AJP701, AJP702, Exp. Dec-2018; AJP601, Exp. Jul-2018; AJP703, Exp. Aug-2019	Failed Impurities/Degradation Specifications: High out of specification results for an impurity.	Sagent Pharmaceuticals Inc
Drugs	Oxytocin USP, powder, 1g-bottle, API American Pharmaceutical Ingredients, NDC 58597-7042-3	Class II	Lot 012517-1R	Stability Data Does Not Support Expiry: Stability data from manufacturer does not support expiration dates listed.	American Pharmaceutical Ingredients LLC
Drugs	Sermorelin Acetate, powder, a) 1 GM-bottle (NDC58597-8092-1) b) 5 GM-bottle (NDC 58597-8092-2) c) 10 GM-bottle (NDC 58597-8092-4) API American Pharmaceutical Ingredients	Class II	Lots: 071916-1, Exp. 07/08/2018; 080516-1, 080516-2, Exp. 07/22/2018; 101216-1, 011917C-1, Exp. 09/15/2018;	Stability Data Does Not Support Expiry: Stability data from manufacturer does not support expiration dates listed.	American Pharmaceutical Ingredients LLC
Drugs	Metformin Hydrochloride Tablets, USP 1000 mg, 500-count bottles, Rx Only, Manufactured for: Aurobindo Pharma USA, Inc. 2400 Route 130 North Dayton, NJ 08810, Manufactured by: Aurobindo Pharma Limited Unit -VII (SEZ) Mahabubnagar (Dt)_509302 India, NDC 65862-010-05.	Class III	Lot#: MTSC17145-A, Exp. July 2021	Presence of Foreign Tablet: Metformin BP 1000mg was found in bottle of Metformin HCl 1000mg	Aurobindo Pharma Ltd.

Product Type	Product Description	Class	Code Info	Reason for Recall	Recalling Firm
Drugs	Calcium Acetate Capsules, 667 mg, 200 Capsules per bottle, Rx Only. Manufactured by Nostrum Laboratories, Inc. Kansas City, MO 64120. NDC 29033-026-02	Class III	Lot: CAL173502; Exp. 09/19	Presence of Foreign Tablets/Capsules	Nostrum Laboratories Inc
Drugs	Cystaran (cysteamine ophthalmic solution) 0.44%, 15 mL bottle, Rx only, Manufactured by Hi-Tech Pharmacal Co. Inc., Amityville, NY 11701 for Leadiant Biosciences, Inc., Gaithersburg, MD 20878, NDC 54482-020-01	Class III	Lot #: 356075, Exp 2/28/18	Subpotent Drug: Out of specification for an active ingredient cysteamine hydrochloride.	LEADIAN T BIOSCIENCES, INC
Drugs	labetalol HCl injection 20 mg/4 mL (5mg/mL), 4 mL syringe, Rx Only, for IV Use, SCA Pharmaceuticals, Windsor, CT 06095 --- NDC 70004-0700-28, UPC 70004070028	Class III	lot 1217000213, expr 03/27/2019	Labeling; Incorrect or Missing Lot number/Expiration Date; some product labels incorrectly indicates a compounding date of 12/27/2018 and use-by date of 03/27/2019 instead of 12/27/2017 and use-by-date of 03/27/2018	SCA Pharmaceuticals, LLC.
Drugs	Atropine Sulfate Ophthalmic 1% Solution, USP, 5mL per bottle, Sterile, Rx Only, Manufactured by: Akorn, Inc., Lake Forest, IL 60045. NDC: 17478-215-05	Class III	Lot: 011037A	Failed Stability Specification: OOS low viscosity results discovered during retain testing.	Akorn, Inc.

Product Type	Product Description	Class	Code Info	Reason for Recall	Recalling Firm
Drugs	Lynparza (olaparib) capsules 50 mg, 112 count bottles, Rx only, Manufactured for: Astra Zeneca Pharmaceuticals LP Wilmington, DE 19850 by: Patheon Pharmaceuticals, Inc. Cincinnati OH 45237 Product of Switzerland NDC 0310-0657-58	Class III	HN0406 02/2018 JH0341 03/2018 JH0342 03/2018 JH0147 03/2018 JC0391 04/2018 JK0147 04/2018 JL0184 04/2018 JC0402 05/2018	Failed Impurities/Degradation Specifications; elevated levels of quality attribute Form L (polymorph).	AstraZeneca Pharmaceuticals LP
Drugs	Life Brand Clear Action Acne Treatment Concealer Stick (Salicylic acid), 1.9g, Imported for: Shoppers Drug Mart Pharmaprix Toronto, M2J4W8, UPC 057800062653	Class III	Lot #: 060E	Superpotent drug: failed assay throughout the stick after 6 months stability.	Oxygen Development Llc
Drugs	Methylphenidate Hydrochloride Extended-release Tablets, USP, 36 mg, 100-count bottle, Rx only, Trigen Laboratories, LLC Bridgewater, NJ 08807. NDC 13811-708-10	Class III	Lots: 170231B, 170232A, 170233A, 170234A	Subpotent Drug:100-count product bottle labeled as Methylphenidate HCL ER Tablets 36 mg found to contain 1 27 mg Methylphenidate HCL ER Tablet.	Osmotica Pharmaceutical Corp

Product Type	Product Description	Class	Code Info	Reason for Recall	Recalling Firm
Drugs	Lupin Hydrocodone Bitartrate and Homatropine Methylbromide Tablets, USP 5/1.5 mg Rx Only 30 Tablets Manufactured by: Novel Laboratories, Inc. Somerset, NJ 08873 Manufactured for: Lupin Pharmaceuticals, Inc. Baltimore, MD 21202 NDC 43386-118-03 UPC 343386118038	Class III	M16002A (02/2018); M16246A (04/2018); M16246B (04/2018); M16434A (07/2018); M16569A (10/2018); M17015A (01/2019); S700271 (04/2019);	Failed Impurities/Degradation Specifications	Novel Laboratories, Inc.
Drugs	Psoriasis Daytime Relief Cream with Vitamin D & Oatmeal, (Coal Tar 1.25%), packaged in 57 g plastic tubes, Distributed by: ALVA-AMCO Pharmacal Cos., Inc., Niles, IL 60714, USA. NDC 52389-745-56, UPC 0 72959 01045 4.	Class III	Lot #: 61031, 61041, 61051, Exp. 4/30/2018; 61601, 61651, 61751, Exp. 6/30/2018; 61941, Exp. 7/31/2018; 62321, Exp. 8/31/2018; 62561, 62721, Exp. 9/30/2018; 62871, Exp. 10/31/2018; 63331, Exp. 11/30/2018; 72011, 72021, 72131, 72141, Exp. 7/31/2019; 72221, 72441, Exp. 8/31/2019; 72921, Exp. 10/31/2019; 73351, Exp. 11/30/2019	Subpotent Drug: The product has failed to maintain its label claim of coal tar throughout its labeled 24-month expiry period.	Alva-Amco Pharmacal Companies, Inc.

Product Type	Product Description	Class	Code Info	Reason for Recall	Recalling Firm
Drugs	Clocortolone Pivalate Cream, 0.1%, 90-gram tube, Rx only, Distributed by: Dr. Reddy's Laboratories, Inc. Princeton, NJ 08540, Manufactured by: DPT, Laboratories Ltd. San Antonio, TX 78215, NDC 43598-341-90	Class III	Lot # MGEC	Failed Stability Specifications: Out-of-specification results observed for viscosity during stability testing.	Dr. Reddy's Laboratories, Inc.

CURRENT DRUG SHORTAGES

Amiodarone Injection

February 20, 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

- Fresenius Kabi has amiodarone 50 mg/mL 9 mL vials available with an expiration date of <9 months.
- West-Ward has amiodarone 50 mg/mL 3 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=1300>

Dalbavancin Injection

February 20, 2018

Reason for the Shortage

- Allergan has Dalvance on shortage due to manufacturing delays. They are the sole suppliers of dalbavancin injection.

Estimated Resupply Dates

- Allergan has Dalvance 500 mg vials on back order and the company estimates a release date of May 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1315>

Diazepam Injection

February 20, 2018

Reason for the Shortage

- Pfizer has diazepam on shortage due manufacturing delays.

Estimated Resupply Dates

- Pfizer has diazepam 5 mg/mL 2 mL Carpuject 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=492>

Clindamycin Injection

February 22, 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.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1029>

Metronidazole Hydrochloride Injection**February 22, 2018****Reason for the Shortage**

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

Estimated Resupply Dates

- Baxter has metronidazole 100 mL bags on allocation only through direct orders.
- BBraun has metronidazole 100 mL bags on back order and the company cannot estimate a release date.
- Claris has metronidazole 100 mL bags on long-term back order and the company cannot estimate a release date.
- Pfizer has metronidazole 100 mL bags in 24 count and 80 count on back order and the company estimates a release date of early-April 2018 for the 24 count presentations and March 2018 for the 80 count presentations.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1272>

Sodium Acetate Injection**February 22, 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

- Pfizer has sodium acetate 2 meq/mL 20 mL vials on back order and the company estimates a release date of mid-March 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=762>

Ammonium Molybdate Injection**February 25, 2018****Reason for the Shortage**

- American Regent has ammonium molybdate injection on shortage due to manufacturing delays.
- American Regent is the sole supplier of ammonium molybdate injection.

Estimated Resupply Dates

- American Regent has ammonium molybdate 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=1003>

Caffeine and Sodium Benzoate Injection**February 25, 2018**

Reason for the Shortage

- American Regent has caffeine and sodium benzoate on shortage due to manufacturing delays.

Estimated Resupply Dates

- American Regent has caffeine and sodium benzoate injection on back order and the company estimates a release date of late-April 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=817>

Dipyridamole Injection**February 25, 2018**

Reason for the Shortage

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

Estimated Resupply Dates

- West-Ward has dipyridamole 5 mg/mL 10 mL vials on allocation.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=465>

Selenium Injection**February 25, 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.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=784>

Sodium Phosphate Injection**February 25, 2018**

Reason for the Shortage

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

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.
- Fresenius Kabi has sodium phosphate 3 mmol/mL 5 mL vials on intermittent back order and the company is releasing product as it becomes available.
- Pfizer has sodium phosphate 3 mmol/mL 15 mL vials on back order and the company estimates a release date of mid-April 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=770>

Cefepime Injection**February 26, 2018**

Reason for the Shortage

- Apotex has updated their cefepime products with new NDC numbers. Supply of the discontinued NDCs may still be available at wholesalers.
- 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 had 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

- BBraun has cefepime 1 gram and 2 gram premixed bags on allocation to current customers.
- Pfizer has cefepime 1 gram and 2 gram ADD-Vantage vials on back order and the company estimates a release date of early-June 2018 for the 1 gram vials and March 2018 for the 2 gram vials. The 1 gram regular 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=1176>

Deferoxamine Injection**February 26, 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 late-March 2018. The 500 mg vials are available with an expiration date of <8 months.
- Pfizer has deferoxamine 500 mg and 2 gram vials on back order and the company estimates a release date of March 2019.
- Novartis has Desferal 500 mg vials available in limited supply.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1312>

Thiamine Injection**February 26, 2018**

Reason for the Shortage

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

Estimated Resupply Dates

- Fresenius Kabi has thiamine 100 mg/mL 2 mL vials on back order and the company estimates a release date of mid-March 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1309>

0.9% Sodium Chloride Small Volume Bags (<150 mL)**February 28, 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 allocation.
- ICU Medical has all 0.9% sodium chloride small volume bags on intermittent back order and the company is releasing supplies as they become available.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1287>

Amino Acid Products**February 28, 2018**

Reason for the Shortage

- 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.
- 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.

Estimated Resupply Dates

- Baxter has their amino acid products on allocation.
- BBraun has their amino acid products on allocation.
- Pfizer has Aminosyn II 15% 2000 mL bags and 10% 2000 mL bags on back order and the company estimates a release date of late-February 2018 for the 15% 2000 mL bags and late-March 2018 for the 2000 mL bags. Amino-F 10% 1000 mL bags are on back order and the company estimates a release date in late-March 2018. All other Aminosyn presentations are on back order and the company estimates a release date in 1st quarter 2019.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=671>

Amino Acid Products with Electrolytes in Dextrose with Calcium (Clinimix E)**February 28, 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.
- 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.

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=1024>

Amino Acids in Dextrose

February 28, 2018

Reason for the Shortage

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

Estimated Resupply Dates

- Baxter has Clinimix 2.75%/5% in 1000 mL bags, 4.25%/5% in 1000 mL bags, 4.25%/10% in 2000 mL bags, 4.25%/20% in 1000 mL and 2000 mL bags, 4.25%/25% in 1000 mL and 2000 mL bags, 5%/15% in 1000 mL bags, 5%/20% in 1000 mL bags, and 5%/25% in 1000 mL and 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=1290>

Heparin Injection

February 28, 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 has all heparin presentations available.
- West-Ward did not provide a reason for the shortage.

Estimated Resupply Dates

- Pfizer has 5,000 unit/mL 1 mL Carpuject syringes on back order and the company estimates a release date of June 2019. The 5,000 unit/mL 10 mL vials are on back order and the company estimates a release date in mid-March 2018. The 30 mL glass vials are on back order and the company estimates a release date of late-March 2018. The 1,000 unit/mL 10 mL vials, 10,000 unit/mL 1 mL vials, and 1,000 unit/mL 30 mL vials are on back order and the company cannot estimate a release date.
- Sagent has 1,000 unit/mL 2 mL vials, 5,000 unit/mL 1 mL vials, and 10,000 unit/mL 1 mL vials on back order and the company estimates a release date of March 2018. The 1,000 unit/mL 10 mL vials are on back order and the company estimates a release date of March 2018. The 20,000 unit/mL 1 mL vials are on allocation.
- West-Ward has 1,000 mL 30 mL vials and 5,000 unit/mL 10 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=1289>

Multiple Electrolytes Large Volume Solutions for Injection

February 28, 2018

Reason for the Shortage

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

Estimated Resupply Dates

- Baxter has Plasma-Lyte-148 500 mL and 1,000 mL bags and Plasma-Lyte-A 500 mL bags available in limited quantities.
- ICU Medical has Normosol-R and Normosol-R (pH 7.4) 1,000 mL bags available in limited quantities.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1310>

Multivitamin Oral Liquid**February 28, 2018**

Reason for the Shortage

- Major has CertaVite with Antioxidants on shortage due to a recall. Products manufactured by PharmaTech LLC were recalled in August 2017 due to potential contamination with Burkholderia cepacia.
- Pfizer did not provide a reason for the shortage.
- Rugby has Cerovite liquid on shortage due to the PharmaTech recall.

Estimated Resupply Dates

- Major has CertaVite with Antioxidants on back order and the company cannot estimate a release date.
- Pfizer has Centrum Liquid on back order and the company estimates a release date in March 2018.
- Rugby has Cerovite liquid on back order and the company cannot estimate a release date.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1257>

Sincalide Injection**February 28, 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 back order and the company cannot estimate a release date.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1032>

5% Dextrose Injection**March 1, 2018**

Reason for the Shortage

- ICU Medical states the shortage was due to increased demand.
- ICU Medical is now the IV fluid business of Pfizer after the acquisition of Hospira.
- Baxter did not provide a reason for the shortage.
- 5% dextrose 1,000-mL bags are not affected at this time.

Estimated Resupply Dates

- Baxter has 5% dextrose 250 mL, 500 mL, and 1,000 mL bags on allocation.
- ICU Medical has 5% dextrose 250 mL 2 port bags (NDC 00409-7922-53 and NDC 00409-7922-02) and 500 mL 2 port bags on back order and the company estimates a release date in mid-March 2018. The 500 mL bags and 1000 mL bags are on intermittent back order and the company is releasing product as it becomes available. The 5% dextrose 250 mL ADD-Vantage bags are on allocation.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1268>

5% Dextrose Injection (PVC-free and DEHP-free)**March 1, 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, 100 mL, and 250 mL PVC/DEHP-free bags on back order and the company estimates a release date in mid-March 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1269>

Alcohol Dehydrated Injection (Ethanol)

March 1, 2018

Reason for the Shortage

- Akorn states the back order was due to manufacturing delays.
- Flon Laboratoris has dehydrated alcohol available. It is being marketed by MHC Pharma, LLC.

Estimated Resupply Dates

- American Regent has dehydrated alcohol 1 mL and 5 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=778>

Lorazepam Oral Solution

March 1, 2018

Reason for the Shortage

- No information available.

Estimated Resupply Dates

- Akorn has lorazepam 2 mg/mL 30 mL bottles on back order and the company estimates a release date of mid-April 2018.
- Amneal has lorazepam 2 mg/mL 30 mL bottles on allocation.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1308>

Penicillamine

March 1, 2018

Reason for the Shortage

- Mylan did not provide a reason for the shortage.

Estimated Resupply Dates

- Mylan has Depen tablets available with an expiration date of September 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1304>

23.4% Sodium Chloride Injection

March 2, 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 intermittent back order and the company is releasing product as it becomes available.
- Pfizer has 23.4% sodium chloride 200 mL vials on back order and the company estimates a release date of mid-April 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1279>

Ceftriaxone Sodium Injection**March 2, 2018****Reason for the Shortage**

- Apotex states the reason for the shortage is manufacturing delays. Apotex launched several products with new NDC numbers in June 2017.
- Fresenius Kabi states the reason for the shortage is increased demand.
- Pfizer has ceftriaxone injection available.
- Sagent states the reason for the shortage is manufacturing delay.
- Sandoz has most ceftriaxone available.
- West-Ward states the reason for the shortage is manufacturing delay.
- WG Critical Care states the reason for the shortage is increased demand.
- Wockhardt relaunched their ceftriaxone presentations in October 2017.

Estimated Resupply Dates

- Apotex has most ceftriaxone presentations on intermittent back order and the company is releasing supplies as they become available.
- Fresenius Kabi has ceftriaxone 500 mg vials on back order and the company cannot estimate a release date.
- Lupin has all ceftriaxone presentations on allocation.
- Pfizer has ceftriaxone 1 gram ADD-Vantage and 2 gram ADD-Vantage vials on allocation.
- Sagent has ceftriaxone 2 gram vials on back order and the company estimates a release date in April 2018.
- Sandoz has ceftriaxone 10 gram vials on back order and the company estimates a release date in late-March 2018.
- Wockhardt has ceftriaxone 2 gram 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=1101>

Labetalol Injection**March 2, 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

- Use Carpuject syringes when possible to conserve labetalol vials for continuous infusions and large intermittent doses.
- Intravenous labetalol is used a first-line agent in treating hypertensive emergency in pregnancy. Other appropriate options in treating hypertensive emergency in pregnant patients are intravenous hydralazine and oral nifedipine.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=397>

Mepivacaine Injection

March 2, 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

- Pfizer has Carbocaine 2% 20 mL preservative-free vials available in limited supply. Carbocaine 1% 30 mL preservative-free vials, 1% 50 mL multiple-dose vials, and 1.5% 30 mL preservative-free vials are on back order and the company estimates a release date of March 2019.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=954>

Prothrombin Complex Concentrate (Kcentra)

March 2, 2018

Reason for the Shortage

- CSL Behring had short-term delays in product releases.

Estimated Resupply Dates

- CSL Behring has Kcentra on intermittent back order with regular releases.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1317>

Sufentanil Injection

March 2, 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 2 mL vials on back order and the company estimates a release date of March 2018.
- Akorn has Sufenta 50 mcg/mL 2 mL ampules on back order and the company estimates a release date of late-March 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=823>

Atropine Sulfate Injection

March 6, 2018

Reason for the Shortage

- American Regent had atropine injection on shortage due to market demand.
- Pfizer has atropine injection on shortage due to manufacturing delays.
- West-Ward did not provide a reason for the shortage.

Estimated Resupply Dates

- American Regent has 0.4 mg/mL 1 mL vials and 1 mg/mL 1 mL vials available in limited quantities.
- Pfizer has atropine 0.1 mg/mL 10 mL Ansyr syringes available on back order and the company estimates a release date of early-June 2018. The 0.1 mg/mL 5 mL LifeShield syringes are on back order and the company estimates a release date of early-April 2018. The 0.1 mg/mL 10 mL LifeShield syringes are on back order and the company estimates a release date of mid-April 2018.
- West-Ward has atropine 0.4 mg/mL 20 mL vials on allocation.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=814>

Bumetanide Injection

March 6, 2018

Reason for the Shortage

- Pfizer has bumetanide injection on shortage due to manufacturing delays.
- West-Ward did not provide a reason for the shortage.

Estimated Resupply Dates

- Pfizer has bumetanide 0.25 mg/mL 4 mL and 10 mL vials on back order and the company estimates a release date of June 2019.
- West-Ward has bumetanide 0.25 mg/mL 4 mL and 10 mL vials on a weekly allocation.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=674>

Calcium Chloride Injection

March 6, 2018

Reason for the Shortage

- American Regent had calcium chloride on shortage due to manufacturing delays.
- Amphastar has calcium chloride on shortage due to increased demand.
- 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 Date

- Amphastar has calcium chloride 100 mg/mL 10 mL syringes on intermittent back order with regular releases.
- Pfizer has calcium chloride 100 mg/mL 10 mL Ansyr syringes on back order and the company estimates a release date of late-May 2018. The 100 mg/mL 10 mL LifeShield syringes are on back order and the company estimates a release date of late-March 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=941>

Dextrose (25%) Injection

March 6, 2018

Reason for the Shortage

- Pfizer had 25% dextrose injection on shortage due to manufacturing delays.

Estimated Resupply Dates

- Pfizer has 25% dextrose 10 mL Ansyr syringes available.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1011>

Dextrose (50%) Injection**March 6, 2018**

Reason for the Shortage

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

Estimated Resupply Dates

- Amphastar has 50% dextrose 50 mL syringes on allocation and is regularly releasing product.
- Pfizer has 50% dextrose 50 mL LifeShield syringes on back order and the company estimates a release date of mid-April 2018. The 50% dextrose 50 mL vials are on back order and the company estimates a release date of late-March 2018. The 50% dextrose 50 mL Ansyr II syringes are on back order and the company estimates a release date of early-April 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1012>

Dobutamine Injection**March 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

- Baxter has all dobutamine premixed bags on allocation only through direct orders. Product is not available through wholesalers.
- Pfizer has dobutamine 12.5 mg/mL 20 mL and 40 mL latex-free vials on back order with an estimated release date of June 2019 for the 20 mL vials and 2018 for the 40 mL vials. The 12.5 mg/mL 20 mL regular vials in 1 count are on back order and the company estimates a release date of late-March 2018.
- Pfizer has dobutamine 1 mg/mL in 250 mL bags on back order and the company estimates a release date of early-May 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 late-May 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=929>

Magnesium Sulfate Injection**March 6, 2018**

Reason for the Shortage

- American Regent has had magnesium sulfate unavailable since late 2012.
- Fresenius Kabi had 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 has magnesium sulfate injection available.

Estimated Resupply Dates

- Fresenius Kabi has magnesium sulfate 500 mg/mL 20 mL and 50 mL vials on back order and the company estimates a release date of late-April 2018. The 40 mg/mL 500 mL and 1,000 mL premixed bags are available with expiration dates of <2 months for the 500 mL premixed bags and <4 months for the 1,000 mL premixed bags. The 40 mg/mL 100 mL premixed bags are on back order and the company estimates a release date of late-April 2018.
- Pfizer has magnesium sulfate 500 mg/mL 20 mL vials on back order and the company estimates a release date of

June 2018. The 500 mg/mL 10 mL syringes are on back order and the company estimates a release date of September 2018. The magnesium sulfate 40 mg/mL 50 mL, 100 mL, 500 mL, and 1,000 mL bags are on back order and the company estimates a release date of early-April 2018 for the 50 mL bags, late-May 2018 for the 100 mL bags, early-May 2018 for the 500 mL bags, and late-March 2018 for the 1,000 mL bags.

- X-Gen has 500 mg/mL 10 mL vials available in limited supply.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=757>

Meperidine Hydrochloride Injection

March 6, 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 50 mg/mL 0.5 mL ampules 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 June 2019. The 50 mg/mL 30 mL vials are on back order and the company estimates a release date of September 2018. The 50 mg/mL 1 mL ampules and 100 mg/mL 1 mL ampules are on back order and the company estimates a release date of early-June 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1285>

Nitroglycerin Injection

March 6, 2018

Reason for the Shortage

- American Regent did not provide a reason for the shortage.
- The premixed bags are not affected by this shortage.

Estimated Resupply Dates

- American Regent has nitroglycerin 50 mg/mL 10 mL vials available.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=786>

Norepinephrine Bitartrate Injection

March 6, 2018

Reason for the Shortage

- Claris has norepinephrine injection available.
- Pfizer has Levophed on shortage due to manufacturing delays.
- Teva has norepinephrine injection on allocation due to increased demand.

Estimated Resupply Dates

- Pfizer has Levophed 1 mg/mL 4 mL ampules on back order and the company estimates a release date of 2020. The 4 mL vials are on allocation.
- Teva has norepinephrine 1 mg/mL 4 mL vials on allocation.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1262>

Potassium Acetate Injection

March 6, 2018

Reason for the Shortage

- American Regent has not had product available for several years. It is unclear if they will market potassium acetate again in the future.
- Pfizer has potassium acetate on shortage due to manufacturing delays.

Estimated Resupply Dates

- Pfizer has potassium acetate 2 mEq/mL 20 mL vials available in limited supply.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=668>

Cefotaxime Injection

March 7, 2018

Reason for the Shortage

- Hospira has discontinued Claforan. Sanofi-Aventis manufactured Claforan for Hospira and is no longer making the product.
- Baxter discontinued Claforan in late-2015.
- West-Ward has cefotaxime on shortage due to manufacturing and issues with raw material.

Estimated Resupply Dates

- West-Ward has cefotaxime 500 mg, 1 gram, 2 gram, and 10 gram vials 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=826>

Disopyramide Phosphate Controlled-release Capsules

March 7, 2018

Reason for the Shortage

- Pfizer has disopyramide controlled-release capsules on shortage due to manufacturing delays.

Estimated Resupply Dates

- Pfizer has Norpace CR 100 mg capsules in 500 count and 150 mg capsules in 500 count on back order and the company cannot estimate a release date.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1139>

Dopamine Hydrochloride Injection

March 7, 2018

Reason for the Shortage

- American Regent has dopamine on shortage due to manufacturing delays.
- Baxter has all dopamine presentations on shortage due to manufacturing delays.
- Pfizer states the shortage is due to manufacturing delays. The dopamine 200 mg/250 mL and 400 mg/500 mL premixed bags were discontinued in August 2017.

Estimated Resupply Dates

- American Regent has all dopamine presentations on back order and the company cannot estimate a release date.

- Baxter has all dopamine premixed bags on allocation only through direct orders. Product is not available through wholesalers.
- Pfizer has dopamine 40 mg/mL 10 mL vials on back order and the company estimates a release date of June 2019. The 400 mg/250 mL bags are on back order and the company estimates a release date of late-March 2018. The 800 mg/250 mL premixed bags are on back order and the company estimates a release date of early-April 2018. The 40 mg/mL 5 mL vials are on back order and the company estimates a release date of late-April 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1243>

Doxorubicin Injection

March 7, 2018

Reason for the Shortage

- West-Ward has Adriamycin available.
- Teva has doxorubicin solution for injection available.
- 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.
- Actavis had doxorubicin on shortage due to increased demand.
- 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. 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 available with an expiration date of August 2018. The 50 mg vials are available with an expiration date of January 2019.
- Pfizer has doxorubicin 2 mg/mL 100 mL vials on back order and the company estimates a release date of early-May 2018 for the 100 mL vials. The 2 mg/mL 25 mL vials and 75 mL vials are on back order and the company estimates a release date in early-April 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=464>

Doxycycline Hyclate Injection

March 7, 2018

Reason for the Shortage

- Mylan Institutional temporarily discontinued doxycycline 100 mg vials in March 2016.
- Fresenius Kabi has doxycycline injection on shortage due to increased demand.

Estimated Resupply Dates

- Fresenius Kabi has doxycycline 100 mg vials available.

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

Furosemide Injection**February 6, 2018**

Reason for the Shortage

- American Regent is not actively marketing furosemide injection.
- Pfizer has furosemide injection on shortage due to manufacturing delays and increased demand.
- Claris has furosemide injection available.
- Fresenius Kabi has furosemide injection available

Estimated Resupply Dates

- Claris has furosemide 10 mg/mL 4 mL and 10 mL vials in 5 counts on back order and the company cannot estimate a release date. The 10 mg/mL 2 mL vials in 5 counts are available with an expiration date of May 2018.
- Fresenius Kabi has furosemide 10 mg/mL 2 mL vials on back order and the company estimates a release date of mid-February 2018.
- Pfizer has furosemide 10 mg/mL 4 mL syringes on back order and the company estimates a release date of late-February 2018. The 2 mL vials and 10 mL syringes are available in limited supply.
- <https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=636>

Furosemide Injection**March 7, 2018**

Reason for the Shortage

- American Regent is not actively marketing furosemide injection.
- Claris has furosemide injection available.
- Fresenius Kabi has furosemide injection available.
- Heritage has furosemide injection available.
- Pfizer has furosemide injection on shortage due to manufacturing delays and increased demand.

Estimated Resupply Dates

- Claris has furosemide 10 mg/mL 4 mL and 10 mL vials in 5 count on back order and the company cannot estimate a release date. The 10 mg/mL 2 mL vials in 5 count are available with an expiration date of May 2018.
- Pfizer has furosemide 10 mg/mL 4 mL syringes on back order and the company estimates a release date of early-April 2018. The 2 mL vials are available in limited supply.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=636>**Hydromorphone Hydrochloride Injection****March 7, 2018**

Reason for the Shortage

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

Estimated Resupply Dates

- Akorn has hydromorphone 10 mg/mL 1 mL ampules, 5 mL ampules, and 50 mL vials on allocation.

- Fresenius Kabi has Dilaudid 0.5 mg/mL 0.5 mL syringes on back order and the company estimates a release date of mid-April 2018. The 1 mg/mL 1 mL syringes, 2 mg/mL 1 mL syringes, and 4 mg/mL 1 mL syringes are on back order and the company cannot estimate a release date.
- Pfizer has 2 mg/mL 1 mL vials on back order and the company estimates a release date of late-April 2018. The 10 mg/mL 1 mL vials are on back order and the company estimates a release date of early-April 2018. The 10 mg/mL 5 mL and 50 mL vials are on back order and the company estimates a release date of September 2018. The 1 mg/mL 1 mL Carpuject syringes, 2 mg/mL 1 mL Carpuject syringes, 0.5 mg/0.5 mL 0.5 mL iSecure syringes, 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.
- 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.
- West-Ward has hydromorphone 2 mg/mL 1 mL vials on allocation. The 2 mg/mL 20 mL vials are on back order and the company estimates a release date of March 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=856>

Lorazepam Injection

March 7, 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 1 and 10 mL vials are on back order and the company estimates a release date of early-April 2018 for the 1 mL vials and June 2018 for the 10 mL vials. The 4 mg/mL 1 mL vials are on back order and the company estimates a release date of early-May 2018. The 4 mg/mL 1 mL Carpuject syringes are on back order and the company estimates a release date of June 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 in mid- to late-March 2018. The 4 mg/mL 1 mL and 10 mL vials are on back order and the company estimates a release date of mid- to late-March 2018 for the 1 mL vials and late-March to late-April 2018 for the 10 mL vials.
- West-Ward has Ativan 2 mg/mL 1 mL and 10 mL vials on back order and the company estimates a release date of late-March to late-April 2018. Ativan 4 mg/mL 1 mL and 10 mL vials are on back order and the company estimates a release date in mid- to late March 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1270>

Methotrexate Injection

March 7, 2018

Reason for the Shortage

- Accord did not provide a reason for the shortage.
- Fresenius Kabi has methotrexate injection available.
- Mylan Institutional did not provide a reason for the shortage. Mylan Institutional discontinued the 40 mg/mL 2

mL and 4 mL vials in late-2017.

- Pfizer has methotrexate injection available.
- Teva had methotrexate injection on shortage due to increased demand.

Estimated Resupply Dates

- Accord has methotrexate 25 mg/mL 2 mL, 10 mL, and 40 mL vials on back order and the company cannot estimate a release date.
- Fresenius Kabi has methotrexate lyophilized powder in 1 gram vials on back order and the company estimates a release date in early-April 2018.

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

Pantoprazole Injection

March 7, 2018

Reason for the Shortage

- Pfizer has Protonix injection on shortage due to manufacturing delays.
- AuroMedics has pantoprazole injection available.
- West-Ward has pantoprazole injection available.

Estimated Resupply Dates

- Pfizer has Protonix 40 mg vials in 25 count packs on back order and the company estimates a release date of mid-March 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1153>

Vancomycin Hydrochloride Injection

March 7, 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 1 gram, 5 gram and 10 gram vials on intermittent back order with regular releases.
- Pfizer has vancomycin 500 mg vials, 1 gram vials, 5 gram vials, and 10 gram vials available in limited supply. The 500 mg ADD-Vantage vials, 750 mg vials, and 750 mg ADD-Vantage vials are on back order and the company estimates a release date of late-April 2018. The 1 gram ADD-Vantage vials are on back order and the company estimates a release date in early-April 2018.
- Sagent has vancomycin 5 gram vials on allocation. The 10 gram vials are on back order and the company estimates a release date of March 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=132>

Amoxapine Tablets**March 8, 2018**

Reason for the Shortage

- Teva did not provide a reason for the shortage.
- Teva is the sole supplier of amoxapine.

Estimated Resupply Dates

- Teva has amoxapine tablets on back order and the company estimates a release date in late-March 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1297>

Fentanyl Citrate Injection**March 8, 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 25 count and 5 mL ampules in 10 count and 25 count on allocation.
- Pfizer has fentanyl 50 mcg/mL 2 mL and 5 mL ampules on back order and the company estimates a release date of mid-April 2018. 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 late-March 2018 for the 2 mL vials, mid-March 2018 for the 5 mL vials, June 2018 for the 10 mL vials, early-April 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 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=1273>

Morphine Injections**March 8, 2018**

Reason for the Shortage

- Fresenius Kabi procured morphine syringes from BD in 2016.
- Astramorph injection has been unavailable since 2012. Fresenius Kabi changed manufacturing sites and cannot estimate if Astramorph will return.
- Pfizer states the shortage is due to manufacturing delays. Pfizer discontinued morphine ADD-Vantage vials in January 2017.
- 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.
- 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.

Estimated Resupply Dates

- Fresenius Kabi has morphine 2 mg/mL 1 mL syringes and 4 mg/mL 1 mL syringes on back order and the company estimates a release date in late-April 2018 for the 2 mg/mL 1 mL syringes and mid-March 2018 for the 4 mg/mL 1 mL syringes. The morphine 5 mg/mL 1 mL, 8 mg/mL, and 10 mg/mL 1 mL syringes are on back order and the company cannot estimate a release date.
- Pfizer has morphine 2 mg/mL 1 mL Carpuject syringes and 4 mg/mL 1 mL Carpuject syringes on back order and the company cannot estimate a release date. The 0.5 mg/mL 10 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 March 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 and 50 mg/mL 50 mL vials are on back order and the company estimates a release date of mid-April 2018 for the 25 mg/mL 1 mL vials and late-March 2018 for the 50 mg/mL 50 mL vials. The 50 mg/mL 20 mL vials are on back order and the company estimates a release date of April 2018.
- West-Ward has morphine 4 mg/mL 1 mL and 10 mg/mL 1 mL vials on allocation. The 8 mg/mL 1 mL vials are on back order and the company estimates a release date in late-March to late-April 2018. Infumorph 10 mg/mL 20 mL ampules are on back order and the company cannot estimate a release date. Infumorph 25 mg/mL 20 mL ampules are on allocation. Duramorph 0.5 mg/mL and 1 mg/mL 10 mL ampules are on allocation.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=664>

Procainamide Hydrochloride Injection

March 8, 2018

Reason for the Shortage

- Pfizer did not provide a reason for the shortage.
- Nexus Pharmaceuticals launched procainamide injection in October 2017.

Estimated Resupply Dates

- Pfizer has procainamide 100 mg/mL 10 mL vials on back order and the company estimates a release date of late-March 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=868>

Rocuronium Injection

March 8, 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 cannot estimate a release date.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=434>

Vincristine Sulfate Injection**March 8, 2018**

Reason for the Shortage

- Pfizer has vincristine on shortage due to manufacturing delays.
- Teva has Vincasar on shortage due to increased demand.

Estimated Resupply Dates

- Pfizer has vincristine 1 mg/mL 1 mL and 2 mL vials on back order and the company estimates a release date of late-May 2018 for the 1 mL vials and late-March 2018 for the 2 mL vials.
- Teva has Vincasar 1 mg/mL 1 mL and 2 mL vials on allocation. Check wholesaler for availability.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1307>

Ampicillin Sulbactam**March 9, 2018**

Reason for the Shortage

- Pfizer has discontinued generic ampicillin sulbactam.
- Sagent has ampicillin sulbactam vials on back order due to manufacturing delays.
- Sagent has ampicillin sulbactam vials on allocation due to manufacturing delays.
- WG Critical Care states the shortage was due to increased demand.

Estimated Resupply Dates

- AuroMedics has ampicillin sulbactam 1.5 gram, 3 gram, and 15 gram vials on long-term back order and the company cannot estimate a release date.
- Fresenius Kabi has ampicillin sulbactam 1.5 gram, 3 gram, and 15 gram vials on long-term back order and the company cannot estimate a release date.
- Mylan Institutional has ampicillin sulbactam 1.5 gram vials on back order and the company estimates a release date of late-March 2018.
- Sagent has ampicillin sulbactam 15 gram vials available with short expiration dating. The 1.5 gram vials are on back order and the company cannot estimate a release date.
- Sandoz has ampicillin sulbactam 1.5 gram, 3 gram, and 15 gram vials temporarily unavailable and the company cannot estimate a release date.
- West-Ward has ampicillin sulbactam 1.5 gram and 3 gram vials on back order and the company cannot estimate a release date. The 15 gram vials are on back order and the company estimates a release date of April to May 2018.
- WG Critical Care has ampicillin sulbactam 1.5 gram vials on back order and the company estimates a release date of early-April 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=805>

Cefoxitin Sodium Injection**March 9, 2018**

Reason for the Shortage

- Fresenius Kabi and West-Ward did not provide a reason for the shortage.
- Sagent has cefoxitin on shortage due to manufacturing delays.
- BBraun has cefoxitin on allocation due to increased demand.

Estimated Resupply Dates

- Sagent has cefoxitin 1 gram vials on back order and the company cannot estimate a release date.
- West-Ward has cefoxitin 1 gram, 2 gram, and 10 gram vials on back order and the company estimates a release date of March 2018 for the 1 gram vials and cannot estimate a release date for the 2 gram and 10 gram vials.
- BBraun has cefoxitin 1 gram and 2 gram vials on allocation.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1256>

Ceftazidime Injection

March 9, 2018

Reason for the Shortage

- Pfizer has Tazicef available.
- Sagent had ceftazidime injection on shortage due to manufacturing delays.
- Sandoz discontinued ceftazidime 1 gram and 2 gram vials in 2015.
- BBraun had ceftazidime on allocation due to increased demand.
- Teligent discontinued Fortaz 2 gram vials and both 1 gram/50 mL and 2 gram/50 mL premixes in February 2018.
- WG Critical Care has ceftazidime available.

Estimated Resupply Dates

- Pfizer has Tazicef 1 gram ADD-Vantage vials on back order and the company estimates a release date of late-May 2018.
- BBraun has ceftazidime 1 gram/50 mL and 2 gram/50 mL premixed bags on allocation.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=869>

Cefuroxime Sodium Injection

March 9, 2018

Reason for the Shortage

- Sagent did not provide a reason for the shortage.
- Teligent discontinued all Zinacef presentations in February 2018.
- West-Ward did not provide a reason for the cefuroxime injection shortage.

Estimated Resupply Dates

- Sagent has cefuroxime 750 mg and 1.5 gram vials on back order and the company cannot estimate a release date.
- West-Ward has cefuroxime 750 mg vials and 7.5 gram vials available with a short expiration date of March 2018. The 1.5 gram vials are on back order and the company estimates a release date of mid- to late-March 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=990>

Chlorothiazide Sodium Injection

March 9, 2018

Reason for the Shortage

- Akorn has chlorothiazide injection on shortage due to manufacturing delays.
- Sagent has 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 estimates a release date of mid-March 2018.

- Fresenius Kabi has chlorothiazide 500 mg vials on back order and the company estimates a release date of late-March 2018.
- Mylan Institutional has chlorothiazide 500 mg vials on back order and the company estimates a release date of late-March 2018.
- Sagent has chlorothiazide 500 mg vials on allocation.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1296>

Cisplatin Injection

March 9, 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 100 mL and 200 mL vials on back order and the company estimates a release date of early-April 2018 for the 100 mL vials and mid- to late-March 2018 for the 200 mL vials. The 1 mg/mL 50 mL vials are available with short-expiration dating (<8 months).

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=57>

Indomethacin Capsules

March 9, 2018

Reason for the Shortage

- Glenmark had indomethacin on shortage due to manufacturing delays.
- Heritage discontinued all indomethacin presentations in early 2018.
- Mylan did not provide a reason for the shortage.
- Sandoz discontinued indomethacin in mid-2016.
- Teva did not provide a reason for the shortage.

Estimated Resupply Dates

- Mylan has indomethacin 25 mg capsules in 100 count on back order and the company estimates a release date of late-March 2018. The 50 mg capsules in 100 count unit-dose are on back order and the company estimates a release date of early-May 2018. The 50 mg capsules in 500 count are on back order and the company cannot estimate a release date.
- Teva has all indomethacin presentations temporarily unavailable and the company cannot estimate a release date.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1236>

Mannitol Injection

March 9, 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 has 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.
- Fresenius Kabi has mannitol 250 mg/mL 50 mL vials on back order and the company cannot estimate a release date. Check wholesalers for supply.
- ICU Medical has mannitol 200 mg/mL 250 mL and 500 mL premixed bags available in limited supply.
- Pfizer has mannitol 250 mg/mL 50 mL vials on back order and the company estimates a release date of early-April 2018.
- BBraun has mannitol 200 mg/mL 250 mL and 500 mL premixed bags on allocation.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=863>

Metoprolol Injection

March 9, 2018

Reason for the Shortage

- Alvogen has metoprolol injection available.
- American Regent has had metoprolol injection on long-term back order for several years.
- Athenex has metoprolol injection available.
- Claris did not provide a reason for the shortage.
- Fresenius Kabi has metoprolol injection on shortage due to increased demand.
- Mylan Institutional acquired metoprolol injection from Sagent.
- Pfizer has metoprolol injection on shortage due to manufacturing delays.
- West-Ward has metoprolol injection available.

Estimated Resupply Dates

- Claris has metoprolol 1 mg/mL 5 mL vials on back order and the company cannot estimate a release date.
- Fresenius Kabi has metoprolol 1 mg/mL 5 mL vials on back order and the company estimates a release date of late-April to early-May 2018.
- Mylan Institutional has metoprolol 1 mg/mL 5 mL vials available with an expiration date of July 2018.
- Pfizer has metoprolol 1 mg/mL 5 mL ampules on back order and the company estimates a release date of March 2019. The 1 mg/mL 5 mL Carpuject syringes are on back order and the company estimates a release date of June 2019.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=813>

Octreotide Injection

March 9, 2018

Reason for the Shortage

- Fresenius Kabi has octreotide available.
- Mylan Institutional has octreotide available.
- Sagent has octreotide on shortage due to manufacturing delays.
- Sun Pharma did not provide a reason for the shortage.
- Teva has octreotide available.
- Novartis has Sandostatin available.
- West-Ward has octreotide available.

Estimated Resupply Dates

- Sagent has octreotide 50 mcg/mL 1 mL vials on back order and the company estimates a release date of March 2018. The 1,000 mcg/mL 5 mL vials are on allocation.
- Sun Pharma has all octreotide presentations on back order and the company cannot estimate a release date.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=803>

Ondansetron Hydrochloride Injection

March 9, 2018

Reason for the Shortage

- Apotex did not provide a reason for the shortage.
- Athenex has ondansetron injection available.
- 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 did not provide a reason for the shortage.
- West-Ward did not provide a reason for the shortage.
- Novartis did not provide a reason for the shortage.

Estimated Resupply Dates

- Apotex has ondansetron 2 mg/mL 2 mL vials on back order and the company estimates a release date of mid-March 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.
- Heritagene 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 a release date of mid-April 2018 for the 2 mL vials and early-April 2018 for the 20 mL vials.
- Pfizer has ondansetron 2 mg/mL 2 mL vials on back order and the company estimates a release date of late-March 2018. The 2 mg/mL 2 mL iSecure syringes are on back order and the company estimates a release date of June 2019.
- Sagent has ondansetron 2 mg/mL 2 mL vials on back order and the company cannot estimate a release date.
- West-Ward has ondansetron 2 mg/mL 2 mL vials on back order and the company estimates a release date of March 2018.
- Novartis has Zofran 2 mg/mL 20 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=1319>

Oseltamivir Oral Suspension

March 9, 2018

Reason for the Shortage

- Alvogen had oseltamivir oral powder for suspension on shortage due to increased demand.
- Zydus has oseltamivir oral powder for suspension on shortage due to increased demand.
- Genentech has Tamiflu oral powder for suspension available.
- The oral capsules are not affected by this shortage.

Estimated Resupply Dates

- Zydus has oseltamivir oral powder for suspension 6 mg/mL 60 mL bottles on allocation.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1306>

Trace Elements Injection**March 9, 2018**

Reason for the Shortage

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

Estimated Resupply Dates

- American Regent has trace elements-4 pediatric vials on back order and the company cannot estimate a release date. The Multitrace-4 Pediatric 3 mL vials, Multitrace-5 regular 10 mL vials, and Multitrace-5 Concentrate 1 mL vials are available in limited supply.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=785>

0.9% Sodium Chloride 10 mL, 20 mL, and 50 mL Preservative Free Vials and Syringes**March 10, 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 early-April 2018.
- Pfizer has 0.9% sodium chloride preservative free 10 mL LifeShield syringes on back order and the company estimates a release date of late-May 2018. The 10 mL, 20 mL, and 50 mL vials are on back order and the company estimates a release date of late-March 2018 for the 10 mL vials, late-April 2018 for the 20 mL and 50 mL vials.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1276>

Bupivacaine with epinephrine Injection**March 10, 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 available with an expiration date of <6 months. The 0.25% Sensorcaine-MPF with epinephrine 30 mL vials are on back order and the company estimates a release date of late-March 2018. The 0.25% Sensorcaine with epinephrine 50 mL vials are on back order and the company estimates a release date of mid- to late-March 2018. The 0.5% Sensorcaine-MPF with epinephrine 10 mL vials are on back order and the company estimates a release date of early-April 2018. The 0.5% Sensorcaine-MPF with epinephrine 30 mL vials are on back order and the company estimates a release date of mid- to late-March 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 early-April 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 10 mL preservative-free vials are

on back order and the company estimates a release date of mid-April 2018. The 0.25% bupivacaine with epinephrine 50 mL vials are on back order and the company estimates a release date of June 2018. The 0.5% bupivacaine with epinephrine 10 mL preservative-free vials are on back order and the company estimates a release date of March 2019. The 0.5% bupivacaine with epinephrine 30 mL preservative-free vials are on back order and the company estimates a release date of mid-May 2018. The 0.5% bupivacaine with epinephrine 50 mL vials are on back order and the company estimates a release date of early-May 2018. Pfizer has 0.25% bupivacaine with epinephrine 10 mL preservative-free NOVAPLUS vials on back order and the company estimates a release date of September 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 March 2019. The 0.25% Marcaine with epinephrine 50 mL vials are on back order and the company estimates a release date of March 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 March 2019. The 0.5% Marcaine with epinephrine 50 mL vials are on back order and the company estimates a release date of March 2019.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=937>

Calcium Gluconate Injection

March 10, 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 and 50 mL vials on back order and the company estimates a release date of early-April 2018 for the 10 mL vials and late-March 2018 for the 50 mL vials.

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

Epinephrine Injection

March 10, 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 mid-April 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=685>

Etoposide Injection**March 10, 2018**

Reason for the Shortage

- Accord has etoposide on back order due to increased demand.
- Fresenius Kabi has etoposide on back order due to increased demand.
- Teva did not provide a reason for the current shortage.
- Etoposide phosphate powder for injection (Etopophos) is unaffected by this shortage.

Estimated Resupply Dates

- Accord has etoposide 20 mg/mL 5 mL, 25 mL, and 50 mL vials on intermittent back order and the company is releasing product as it becomes available.
- Fresenius Kabi has etoposide 20 mg/mL 5 mL, 25 mL, and 50 mL vials on back order and the company estimates a release date of late-April 2018 for the 5 mL vials and early-April 2018 for the 20 mL and 50 mL vials. Check wholesalers for inventory.
- Teva has Toposar 20 mg/mL 5 mL and 25 mL vials on allocation. 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=652>

Famotidine Injection**March 10, 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 back order and the company estimates a release date of mid- to late-March 2018 for the 2 mL vials and early-April 2018 for the 4 mL vials.
- Mylan Institutional has famotidine 2 mL vials on back order and the company estimates a release date of late-March 2018.
- West-Ward has famotidine 2 mL vials on back order and the company estimates a release date of March 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=810>

Furosemide Tablets**March 10, 2018**

Reason for the Shortage

- Major states the shortage is due to supply and demand issues.
- 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.

Estimated Resupply Dates

- Mylan has furosemide 20 mg tablets in 100 count and 40 mg tablets in 1000 count on back order and the

company estimates a release date of mid- to late-March 2018.

- Teva has furosemide 20 mg and 40 mg tablets in 100 and 1000 count bottles temporarily unavailable and the company cannot estimate a release date.
- 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=1281>

Leuprolide Acetate 14-Day Kit

March 10, 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 intermittent back order with regular releases.
- 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=737>

Torsemide Injection

March 10, 2018

Reason for the Shortage

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

Estimated Resupply Dates

- American Regent has torsemide 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=344>

Carbidopa and Levodopa Extended-Release Tablets

March 12, 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 has 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 back order and the company cannot estimate a release date.
- Sun Pharma has carbidopa and levodopa 25 mg/100 mg and 50 mg/200 mg extended-release tablets available in limited supply.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1181>

Diclofenac 0.1% Ophthalmic Solution

March 12, 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 2.5 mL and 5 mL bottles on back order and the company estimates a release date of March 2018 for the 2.5 mL bottles and mid-March 2018 for the 5 mL bottles.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1313>

Fluorouracil Injection

March 12, 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 available.

Estimated Resupply Dates

- Accord has fluorouracil 50 mg/mL 10 mL, 20 mL, and 100 mL vials on back order and the company estimates a release date of March 2018.
- Fresenius Kabi has fluorouracil 50 mg/mL 50 mL and 100 mL vials on back order and the company estimates a release date of late-March 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=798>

Hydroxyzine Hydrochloride Injection

March 12, 2018

Reason for the Shortage

- American Regent has hydroxyzine injection on shortage due to manufacturing delays. They are the sole supplier of hydroxyzine injection.

Estimated Resupply Dates

- American Regent has hydroxyzine 50 mg/mL 10 mL vials 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=1185>

Ketorolac Injection

March 12, 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 did not provide a reason for the shortage.
- Pfizer has ketorolac injection on back order due to manufacturing delays.
- Sagent states the reason for the shortage is manufacturing delay.
- West-Ward is not actively marketing ketorolac injection.
- 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

- Amphastar has ketorolac 30 mg/mL 1 mL vials on back order and the company cannot estimate a release date.
- Fresenius Kabi has ketorolac 15 mg/mL 1 mL vials on back order and the company estimates a release date of late-March 2018. The 30 mg/mL 1 mL vials and 30 mg/mL 2 mL vials for intramuscular injection are on back order and the company estimates a release date of mid-March 2018.
- Pfizer has ketorolac 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 on back order and the company estimates a release date of June 2019. The 30 mg/mL 1 mL vials are on intermittent back order and the company is releasing supplies as they become available.
- Sagent has ketorolac 30 mg/mL 2 mL vials for intramuscular injection, 15 mg/mL 1 mL vials, and 30 mg/mL 1 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=1320>

Dorzolamide 2% and Timolol 0.5% Ophthalmic Solution

March 13, 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 did not provide a reason for the shortage.
- 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. The company has Cosopt 2%/0.5% ophthalmic solution in 10 mL bottles on back order and the company cannot estimate a release date.
- Sandoz has dorzolamide 2% and timolol 0.5% ophthalmic solution in 10 mL bottles on back order and the company estimates a release date of mid- to late-March 2018.
- Teva 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-April 2018.
- 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-March 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1292>

Dorzolamide Ophthalmic Solution

March 13, 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 did not provide a reason for the shortage.
- Valeant has dorzolamide ophthalmic solution on shortage due to manufacturing delays.

Estimated Resupply Dates

- Akorn has dorzolamide 2% ophthalmic solution on allocation.
- Teva has dorzolamide 2% ophthalmic solution on back order and the company cannot estimate a release date.
- Valeant has dorzolamide 2% ophthalmic solution on back order and the company estimates a release date of early- to mid-April 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1293>

Indocyanine Green**March 13, 2018****Reason for the Shortage**

- Akorn had IC-Green on shortage due to manufacturing delays.
- Hub did not provide a reason for the shortage.

Estimated Resupply Dates

- Akorn has IC-Green 25 mg kits on allocation.
- Hub Pharmaceuticals has indocyanine green on back order and the company estimates a release date of early-April 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1107>

Procainamide Hydrochloride Injection**February 12, 2018****Reason for the Shortage**

- Pfizer did not provide a reason for the shortage.
- Nexus Pharmaceuticals launched procainamide injection in October 2017.

Estimated Resupply Dates

- Pfizer has procainamide 100 mg/mL 10 mL vials on back order and the company estimates a release date of late-March 2018.
- <https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=868>

Leucovorin Calcium Injection**March 13, 2018****Reason for the Shortage**

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

Estimated Resupply Dates

- Fresenius Kabi has leucovorin 500 mg vials on intermittent back order and the company is releasing product as it becomes available. The 200 mg vials are on back order and the company expects a release date of late-March 2018.

- Sagent has leucovorin 350 mg vials on allocation.
- West-Ward has leucovorin 350 mg vials on allocation. The 50 mg and 200 mg vials are on back order and the company expects a release date of second or third quarter of 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=488>

Lidocaine with Epinephrine Injection

March 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 on back order and the company estimates a release date of June 2018. The 1% lidocaine with epinephrine (1:100,000) 20 mL vials are on back order and the company estimates a release date of late-May 2018. The 1% lidocaine with epinephrine (1:100,000) 30 mL and 50 mL vials are on intermittent back order and the company is releasing product as it becomes available. The 1.5% lidocaine with epinephrine (1:200,000) 30 mL vials are on back order and the company estimates a release date of September 2018. The 2% lidocaine with epinephrine (1:200,000) 20 mL vials are on back order and the company estimates a release date of March 2018. The 2% lidocaine with epinephrine (1:100,000) 20 mL, 30 mL, and 50 mL vials are on back order and the company estimates a release date of June 2018 for the 20 mL and 30 mL vials and early-April 2018 for the 50 mL vials.
- Fresenius Kabi has 0.5% Xylocaine with epinephrine (1:200,000) 50 mL vials on back order and the company estimates a release date of early- to mid-April 2018. The 1% Xylocaine with epinephrine (1:200,000) 10 mL, 20 mL, and 50 mL vials are on back order and the company estimates a release date of mid- to late-March 2018. The 1% Xylocaine-MPF with epinephrine (1:200,000) 10 mL and 30 mL vials are on back order and the company estimates a release date of early-April 2018 for the 10 mL vials and mid- to late-March 2018 for the 30 mL vials. 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 are on back order and the company estimates a release date of mid- to late-March 2018. The 1.5% Xylocaine-MPF with epinephrine (1:200,000) 10 mL regular vials and 30 mL vials in sterile packs are on back order and the company cannot estimate a release date. The 2% Xylocaine with epinephrine (1:200,000) 20 mL vials are on intermittent back order and the company is releasing product as it becomes available. The 2% Xylocaine with epinephrine (1:200,000) 50 mL vials are on back order and the company estimates a release date of mid- to late-April 2018. The 2% Xylocaine-MPF with epinephrine (1:200,000) 10 mL and 20 mL vials are on intermittent back order and the company is releasing product as it becomes available. The 2% Xylocaine-MPF with epinephrine (1:200,000) 20 mL vials in sterile packs 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=860>

Acetylcysteine Oral and Inhalation Solution

March 14, 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.

Estimated Resupply Dates

- American Regent has acetylcysteine solution 100 mg/mL 4 mL and 200 mg/mL 4 mL vials available in limited supply. The 100 mg/mL 10 mL and 200 mg/mL 10 mL and 30 mL vials are on back order and the company cannot estimate a release date.
- Fresenius Kabi has acetylcysteine solution 200 mg/mL 4 mL and 30 mL vials on back order and the company estimates a release date of mid- to late-March 2018. The 200 mg/mL 10 mL vials are on back order and the company estimates a release date of mid-April 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-April 2018 for the 4 mL and 30 mL vials and late-April 2018 for the 10 mL vials.
- Pfizer has acetylcysteine solution 100 mg/mL 30 mL vials available in limited supply.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=932>

Azithromycin Injection

March 14, 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 June 2018. Zithromax 500 mg vials are on back order and the company estimates a release date of late-March 2018.
- Sun Pharma has azithromycin 500 mg 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=936>

Bupivacaine Injection

March 14, 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 intermittent back order and the company is releasing product as it becomes available. The 0.5% bupivacaine 10 mL and 30 mL preservative-free vials are on intermittent back order and the company is releasing product as it becomes available.
- Pfizer has 0.25% bupivacaine 10 mL preservative-free vials and 30 mL preservative-free vials on back order and the company estimates a release date in late-March 2018. The 0.5% bupivacaine 10 mL preservative-free vials and 30 mL preservative-free vials are on back order and the company estimates a release date of early-May 2018 for the 10 mL preservative-free vials and early-April 2018 for the 0.5% 10 mL preservative-free vials.
- Pfizer has all Marcaine presentations on back order and the company estimates a release date of March 2019.
- Fresenius Kabi has 0.25% Sensorcaine 30 mL preservative-free vials on back order and the company estimates a release date in mid- to late-March 2018. The 0.25% 50 mL vials are on back order and the company estimates a

release date in mid-April 2018. The 0.5% Sensorcaine 10 mL preservative-free vials are on back order and the company estimates a release date of late-April 2018. The 0.5% Sensorcaine 50 mL vials are on back order and the company estimates a release date of early-April 2018. The 0.5% Sensorcaine 30 mL preservative-free vials in sterile packs 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=864>

Dexamethasone Sodium Phosphate

March 14, 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 and 5 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 available with an expiration date of <4 months.
- Mylan Institutional has dexamethasone 4 mg/mL 1 mL vials on back order and the company estimates a release date of mid-May 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=751>

Diltiazem Hydrochloride Injection

March 14, 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 March 2019.
- West-Ward has diltiazem 5 mg/mL 5 mL and 10 mL vials on back order and the company estimates a release date of late-March to early-April 2018. The 25 mL vials are on allocation.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1271>

Erythromycin Lactobionate Injection**March 14, 2018**

Reason for the Shortage

- Pfizer has Erythrocin on shortage due to manufacturing delays.

Estimated Resupply Dates

- Pfizer has Erythrocin 500 mg ADD-Vantage vials on back order and the company estimates a release date of March 2018. The Erythrocin 500 mg regular vials are on back order and the company estimates a release date of September 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=546>

Etomidate Injection**February 12, 2018**

Reason for the Shortage

- American Regent did not provide a reason for the current shortage.
- AuroMedics did not provide a reason for the current shortage.
- Mylan did not provide a reason for the current shortage.
- Par Sterile Products discontinued etomidate in early 2015.
- Pfizer has Amidate on shortage due to manufacturing delays. Pfizer discontinued etomidate ampules in October 2016.
- Sagent is no longer marketing etomidate.
- West-Ward did not provide a reason for the current shortage.
- Zydus had etomidate on shortage due to an increase in demand.

Estimated Resupply Dates

- American Regent has etomidate 2 mg/mL 10 mL and 20 mL vials on back order and the company cannot estimate a release date.
- AuroMedics has 2 mg/mL 10 mL vials on intermittent back order.
- Mylan Institutional has etomidate 2 mg/mL 10 mL and 20 mL vials on back order and the company estimates a release date of early-August 2018.
- Pfizer has Amidate 2 mg/mL 20 mL LifeShield syringes on back order and the company cannot estimate a release date. The 2 mg/mL 10 mL and 20 mL vials are on back order and the company estimates a release date of late-March 2018 for the 10 mL vials and early-April 2018 for the 20 mL vials.
- West-Ward has etomidate 2 mg/mL 10 mL vials available with short expiration dating (May 2018 and September 2018).
- Zydus has etomidate 2 mg/mL 20 mL vials on intermittent back order.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=419>

Ketamine Injection**March 14, 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 cannot estimate a release date. The 50 mg/mL 10 mL vials are on back order and the company estimates a release date of early-April 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 March 2019.
- West-Ward 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 late-March to early-April 2018.
- 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=592>

Lidocaine Injection

March 14, 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 2 mL and 5 mL ampules and 2mL, 5 mL, and 30 mL vials on intermittent back order and the company is releasing product as it becomes available. AuroMedics has 2% lidocaine 2mL 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 and 0.5% Xylocaine-MPF 50 mL vials on back order and the company estimates a release date of mid-April 2018 for the 0.5% Xylocaine 50 mL vials and early-April 2018 for the 0.5% Xylocaine-MPF 50 mL vials. The 1% lidocaine 10 mL vials are on back order and the company estimates a release date of late-March 2018. The 1% Xylocaine 20 mL and 50 mL vials are on back order and the company estimates a release date of mid-March 2018. The 1% Xylocaine-MPF 2 mL vials and 5 mL vials are on back order and the company estimates a release date of late-March 2018 for the 2 mL vials and mid-March 2018 for the 5 mL vials. The 1% Xylocaine-MPF 10 mL vial and 30 mL vial sterile packs are on back order and the company cannot estimate a release date. The 1.5% Xylocaine-MPF 20 mL ampules are on back order and the company estimates a release date of late-March 2018. The 2% Xylocaine-MPF 2 mL and 5 mL vials are on back order and the company estimates a release date of mid-April 2018 for the 2 mL vials and mid- to late-March 2018 for the 5 mL vials. The 2% Xylocaine 20 mL and 50 mL vials are on back order and the company estimates a release date of late-March 2018 for the 20 mL vials and early-April 2018 for the 50 mL vials. The 2% lidocaine 5 mL preservative free vials are on back order and the company estimates a release date of late-March 2018.
- Pfizer has 0.5% lidocaine 50 mL vials on back order and the company estimates a release date of March 2018. The 2 mL preservative-free ampules are on back order and the company estimates a release date of early-April 2018. The 1% lidocaine 5 mL preservative-free ampules are on back order and the company estimates a release date of June 2019. The 1% lidocaine 20 mL vials are on back order and the company estimates a release date of early-April 2018. The 1% lidocaine 30 mL preservative-free vials are on back order and the company estimates a release date of late-March 2018. The 1% lidocaine 50 mL vials are on back order and the company estimates a release date in June 2018. The 1% lidocaine 5 mL Ansyr syringes are on back order and the company estimates a release date of late-March 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 and 20 mL vials are on back order and the company estimates a release date of late-March 2018. The 2% lidocaine 50 mL vials are on back order and the company estimates a release date of early-May 2018. The 2% lidocaine 5 mL Lifeshield syringes

and 5 mL Ansyf syringes are on back order and the company estimates a release date of early-April 2018. The 4% lidocaine 5 mL ampules are on back order and the company estimates a release date of early-April 2018.

- West-Ward has 1% lidocaine 5 mL preservative-free vials and 2% lidocaine 5 mL preservative free vials on allocation. The 1% lidocaine 50 mL vials are on back order and the company estimates a release date of April to May 2018. The 2% lidocaine 50 mL vials are on back order and the company estimates a release date of late-March to early-April 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=859>

Remifentanil Injection

March 14, 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 1 mg, 2 mg, and 5 mg vials on back order and the company estimates a release date of late-March 2018 for the 1 mg vials and mid-May 2018 for the 2 mg and 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 2nd quarter 2018. Check wholesalers for inventory.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1299>

Ropivacaine Injection

March 14, 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 back order and the company estimates a release date of March 2018.
- AuroMedics has ropivacaine 2 mg/mL 20 mL vials and 100 mL bottles, 5 mg/mL 20 mL and 30 mL vials, 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 June 2018. The 5 mg/mL 30 mL vials are on back order and the company estimates a release date of early-May 2018. The 7.5 mg/mL 20 mL vials are on back order and the company estimates a release date of June 2018. The 10 mg/mL 10 mL and 20 mL vials are on back order and the company estimates a release date of June 2018.
- Fresenius Kabi has Naropin 2 mg/mL 10 mL and 20 mL vials on back order and the company estimates a release date of late-March 2018 for the 10 mL vials and mid- to late-March 2018 for the 20 mL vials. The 2 mg/mL 10 mL Steripak ampules are on back order and the company cannot estimate a release date. The 2 mg/mL 20 mL Steripak ampules are on back order and the company estimates a release date of mid-March 2018. The 2 mg/mL 100 mL and 200 mL bottles are on back order and the company estimates a release date of mid- to late-March 2018 for the 100 mL bottles and late-March 2018 for the 200 mL bottles. The 2 mg/mL 100 mL and 200 mL premixed bags are on back order and the company estimates a release date of mid-March 2018. The 5 mg/mL 10 mL vials are on back order and the company estimates a release date of early- to mid-April 2018. The 5 mg/mL 30

mL Steripak ampules are on back order and the company estimates a release date of late-May 2018. The 5 mg/mL 200 mL bottles are on back order and the company estimates a release date of mid-March 2018. The 7.5 mg/mL 20 mL vials are on back order and the company estimates a release date of mid-April 2018. The 7.5 mg/mL 20 mL Steripak ampules are on back order and the company estimates a release date of mid-May 2018. The 10 mg/mL 10 mL vials are on back order and the company estimates a release date of late-April 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-May 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=854>

0.9% Sodium Chloride Large Volume Bags Injection Bags

March 15, 2018

Reason for the Shortage

- Baxter discontinued 0.9% sodium chloride 250 mL and 500 mL AVIVA bags. The Viaflex bags and Viaflo bags are on allocation.¹
- BBraun did not provide a reason for the shortage.²
- Pfizer cited increased demand as the reason for the shortage.³
- Fresenius Kabi is no longer importing product.⁷
- Baxter has received FDA approval for 0.9% sodium chloride in Viaflo containers manufactured in an FDA-approved facility in Spain.

Estimated Resupply Dates

- Baxter has all 0.9% sodium chloride presentations on allocation.
- BBraun has 0.9% sodium chloride 250 mL, 500 mL, and 1,000 mL PVC/DEHP-free bags on allocation to current customers.
- Pfizer has 0.9% sodium chloride 150 mL and 250 mL bags on allocation. The 500 mL, 1000 mL, 250 mL PVC/DEHP-free, 250 mL 2-port bags, and 500 mL 2-port bags are on intermittent back order and the company is releasing supplies as they become available.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1288>

2% Lidocaine Hydrochloride Topical Jelly

March 15, 2018

Reason for the Shortage

- Akorn has 2% lidocaine jelly on shortage due to increased demand.
- Teva did not provide a reason for the shortage.
- Glydo and Uro-Jet prefilled syringes are not affected by this shortage.

Estimated Resupply Dates

- Akorn has 2% lidocaine jelly 5 mL and 30 mL tubes on allocation.
- Teva has 2% lidocaine jelly 5 mL and 30 mL tubes on back order and the company estimates a release date in late-March 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1316>

Fluconazole Injection

March 15, 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.

Estimated Resupply Dates

- Baxter has 200 mg/100 mL and 400 mg/200 mL in 0.9% sodium chloride premixed bags on back order and the company cannot estimate a release date.
- 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.
- West-Ward has all 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 late-April to May 2018.
- Pfizer has fluconazole 200 mg/100 mL in 5% dextrose premixed bags and 400 mg/200 mL in 5% dextrose premixed bags on back order. The company cannot estimate a release date for the 200 mg/100 mL in 5% dextrose premixed bags, and the company estimates a release date of October 2018 for the 400 mg/200 mL in 5% dextrose premixed bags.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=644>

5% Lidocaine and 7.5% Dextrose Injection

March 19, 2018

Reason for the Shortage

- Pfizer has 5% lidocaine and 7.5% dextrose 2 mL ampules on shortage due to manufacturing delays.
- Pfizer is the sole supplier of this combination.

Estimated Resupply Dates

- Pfizer has 5% lidocaine and 7.5% dextrose 2 mL ampules on long-term back order and the company estimates a release date of January 2019.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1245>

Dexmedetomidine Hydrochloride in 0.9% Sodium Chloride Injection

March 19, 2018

Reason for the Shortage

- Pfizer did not provide a reason for the shortage.

Estimated Resupply Dates

- Pfizer has Precedex 4 mcg/mL 20 mL vials on back order and the company estimates a release date of June 2018. Precedex 4 mcg/mL 50 mL and 100 mL premixed bottles are on allocation.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1263>

Dexpanthenol Injection

March 19, 2018

Reason for the Shortage

- American Regent has dexpanthenol injection on shortage due to manufacturing delays.
- There are no other suppliers of dexpanthenol injection.

Estimated Resupply Dates

- American Regent has dexpanthenol 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=1103>

Fomepizole Injection**March 19, 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

- Mylan Institutional has fomepizole 1 gram/mL 1.5 mL vials on back order and the company estimates a release date of early- to mid-April 2018.
- X-Gen has fomepizole 1 gram/mL 1.5 mL vials on back order and the company estimates a release date of late-March 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1173>

Methyldopate Injection**March 19, 2018****Reason for the Shortage**

- American Regent has methyldopate injection on shortage due to manufacturing delays.
- There are no other suppliers of methyldopate injection.

Estimated Resupply Dates

- American Regent has methyldopate 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=844>

Metoclopramide Injection**March 19, 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.

Estimated Resupply Dates

- Pfizer has metoclopramide 5 mg/mL 2 mL vials on back order and the company estimates a release date of mid-April 2018.
- Teva has metoclopramide 5 mg/mL 2 mL vials on allocation.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=611>

Mitoxantrone Hydrochloride Injection**March 19, 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 and 15 mL vials on back order and the company estimates a release date of mid-May 2018 for the 10 mL vials and late-March 2018 for the 15 mL vials.
- 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=1212>

Pamidronate Disodium Injection

March 19, 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, 6 mg/mL, and 9 mg/mL 10 mL vials on back order and the company estimates a release date of June 2018 for the 3 mg/mL 10 mL vials, April 2018 for the 6 mg/mL 10 mL vials, and May 2018 for the 9 mg/mL 10 mL vials.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1318>

Penicillin G Benzathine/Penicillin G Procaine

March 19, 2018

Reason for the Shortage

- Pfizer has Bicillin C-R on shortage due to manufacturing delays.

Estimated Resupply Dates

- Pfizer has Bicillin C-R 1,200,000 units/2 mL prefilled syringes and 1,200,000 units/2 mL pediatric prefilled syringes on back order and the company estimates a release date of May 2018.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1249>

Haloperidol Lactate Injection

March 20, 2018

Reason for the Shortage

- Mylan Institutional has haloperidol lactate injection available.
- Patriot Pharmaceuticals has haloperidol lactate available.
- Sagent has discontinued haloperidol 5 mg/mL 10 mL vials. The company plans to relaunch the product in May 2018.
- Teva is not currently marketing haloperidol lactate.
- West-Ward is not actively marketing haloperidol lactate at this time.
- Janssen has Haldol injection available.

Estimated Resupply Dates

- Sagent has discontinued haloperidol lactate 5 mg/mL 10 mL vials. The company plans to relaunch the product in May 2018.

- Fresenius Kabi has haloperidol lactate 5 mg/mL 10 mL vials available but with short dating of less than or equal to 7 months.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=527>

Phenytoin Sodium Injection

March 20, 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 100 mg/2 mL and 250 mg/5 mL vials on back order. The company estimates a release date of late-March to mid-April 2018 for the 250 mg/5 mL vials and cannot estimate a release date for the 100 mg/2 mL vials.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1322>

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