



**October 2016**

Drug Information Update

# TABLE OF CONTENTS

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NEWLY AVAILABLE GENERICS .....	2
NEW DRUG ENTITIES/COMBINATIONS/STRENGTHS .....	3
NEW INDICATIONS (EXISTING DRUGS) .....	7
FDA NEWS/BULLETINS/ADVISORIES/SAFETY ALERTS .....	9
STUDIES and RECENT TOPICS .....	11
RECALLS.....	15
CURRENT DRUG SHORTAGES.....	38

## NEWLY AVAILABLE GENERICS

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GENERIC DRUG NAME	STRENGTH & DOSAGE FORM	GENERIC MANUFACTURER	BRAND NAME
Erythromycin Ethylsuccinate	200mg/5ml suspension reconstituted	ANI Pharmaceuticals	E.E.S 200 and Eryped 200
Levalbuterol Tartrate	45mcg/actuation HFA	Actavis Pharma	Xopenex HFA
Neostigmine Methylsulfate	3mg/3mL (1mg/mL) syringe	West Ward Pharmaceuticals	Bloxiverz
Hydrocortisone Acetate	2.5% cream	Perrigo	Micort-HC
Abacavir sulfate/ Lamivudine	600mg-300mg tablet	Teva	Epzicom

## NEW DRUG ENTITIES/COMBINATIONS/STRENGTHS

DESCRIPTION	BRAND NAME	GENERIC NAME	STRENGTH	NOTES
ANTI-OBESITY SEROTONIN 2C RECEPTOR AGONISTS	BELVIQ XR	LORCASERIN HCL	20 mg	New Strength and Dosage Form
TOPICAL ANTI- INFLAMMATORY, NSAIDS	NUDICLO	DICLOFENAC SODIUM/ CAPSAICIN	1.5 %-0.025 %	New Combination
VASODILATORS, CORONARY	GONITRO	NITROGLYCERIN	400 mcg	New Dosage Form
ANTIHYPERGLYCE MIC-SGLT2 INHIBITOR & BIGUANIDE COMB	INVOKAMET XR	CANAGLIFLOZIN/ METFORMIN HCL	50 mg-500 mg	New Dosage Form
ANTIHYPERGLYCE MIC-SGLT2 INHIBITOR & BIGUANIDE COMB	INVOKAMET XR	CANAGLIFLOZIN/ METFORMIN HCL	50 mg-1,000 mg	New Dosage Form
ANTIHYPERGLYCE MIC-SGLT2 INHIBITOR & BIGUANIDE COMB	INVOKAMET XR	CANAGLIFLOZIN/ METFORMIN HCL	50 mg-1,000 mg	New Dosage Form
ANTIHYPERGLYCE MIC-SGLT2 INHIBITOR & BIGUANIDE COMB	INVOKAMET XR	CANAGLIFLOZIN/ METFORMIN HCL	150 mg-1,000 mg	New Dosage Form
CONTRACEPTIVES, ORAL	TAYTULLA	NORETHINDRONE- E.ESTRADIOL-IRON	1 mg-20 mcg (24)/75 mg (4)	New Combination
PLATELET AGGREGATION INHIBITORS	YOSPRALA	ASPIRIN/ OMEPRAZOLE	81 mg-40 mg	New Combination
PLATELET AGGREGATION INHIBITORS	YOSPRALA	ASPIRIN/ OMEPRAZOLE	325 mg-40 mg	New Combination
TOPICAL	DERMACINRX	CLOTRIMAZOLE/	1 %-0.05 %-20 %	New Combination

DESCRIPTION	BRAND NAME	GENERIC NAME	STRENGTH	NOTES
ANTIFUNGAL/ANTI-INFLAMMATORY, STEROID AGENT	THERAZOLE PAK	BETAMETH DIP/ ZINC		
GENETIC D/O TX-EXON SKIPPING ANTISENSE OLIGONUCLEO	EXONDYS 51	ETEPLIRSEN	100 mg/2 mL (50 mg/mL)	New Entity
GENETIC D/O TX-EXON SKIPPING ANTISENSE OLIGONUCLEO	EXONDYS 51	ETEPLIRSEN	500 mg/10 mL (50 mg/mL)	New Entity
ANTISERA	CUVITRU	IMMUN GLOB G(IGG)/GLY/IGA OV50	8 gram/40 mL (20 %)	New Strength
ANTISERA	CUVITRU	IMMUN GLOB G(IGG)/GLY/IGA OV50	1 gram/5 mL (20 %)	New Strength
ANTISERA	CUVITRU	IMMUN GLOB G(IGG)/GLY/IGA OV50	2 gram/10 mL (20 %)	New Strength
ANTISERA	CUVITRU	IMMUN GLOB G(IGG)/GLY/IGA OV50	4 gram/20 mL (20 %)	New Strength
MONOCLONAL ANTIBODY-HUMAN INTERLEUKIN 12/23 INHIB	STELARA	USTEKINUMAB	130 mg/26 mL	New Strength
CYSTIC FIBROSIS-CFTR POTENTIATOR-CORRECTOR COMBIN.	ORKAMBI	LUMACAFTOR/IVA CAFTOR	100-125 MG	New Combination
PRENATAL VITAMIN PREPARATIONS	TRICARE PRENATAL	PRENATAL VIT #113/IRON/FOLAT E	4.5 MG-1MG	New Combination
ANTIMIGRAINE	TREXIMET	SUMATRIPTAN	10 MG-60MG	New Combination

DESCRIPTION	BRAND NAME	GENERIC NAME	STRENGTH	NOTES
PREPARATIONS		SUCC/NAPROXEN SOD		
ANTIEMETIC/ANTI VERTIGO AGENTS	SUSTOL	GRANISETRON	10MG/0.4ML	New Strength and Dosage Form
PHOTOACT, TOPICAL ANTINEOPLAST, PREMALIGNANT LESIONS	AMELUZ	AMINOLEVULINIC ACID HCL	10%	New Strength and Dosage Form
EYE ANTI-INFLAMMATORY AGENTS	BROMSITE	BROMFENAC SODIUM	0.075%	New Strength
VITAMIN D PREPARATIONS	ROXIFOL-D	VITAMIN D3/FOLIC ACID	500 unit-1 mg	New Strength
PANCREATIC ENZYMES	PANCREAZE	LIPASE/PROTEASE/ AMYLASE	4,200 unit-14,200 unit-24,600 unit	Reused NDC with NEW GCN, GCN_SEQNO and MEDID
PANCREATIC ENZYMES	PANCREAZE	LIPASE/PROTEASE/ AMYLASE	10,500 unit-35,500 unit-61,500 unit	Reused NDC with NEW GCN, GCN_SEQNO and MEDID
PANCREATIC ENZYMES	PANCREAZE	LIPASE/PROTEASE/ AMYLASE	16,800 unit-56,800 unit-98,400 unit	Reused NDC with NEW GCN, GCN_SEQNO and MEDID
PANCREATIC ENZYMES	PANCREAZE	LIPASE/PROTEASE/ AMYLASE	21,000 unit-54,700 unit-83,900 unit	Reused NDC with NEW GCN, GCN_SEQNO and MEDID
LIPOTROPICS	VASCEPA	ICOSAPENT ETHYL	0.5 gram	New Strength
TOPICAL ANTI-INFLAMMATORY, NSAIDS	DICLOZOR	DICLOFENAC SODIUM	1 %	New Strength and Dosage Form
TOPICAL LOCAL ANESTHETICS	ANASTIA	LIDOCAINE HCL	2.75 %	New Strength

DESCRIPTION	BRAND NAME	GENERIC NAME	STRENGTH	NOTES
TOPICAL ANTI-INFLAMMATORY STEROIDAL	MICORT-HC	HYDROCORTISONE ACETATE	2.5 % (4 gram)	New Dosage Form
INTRA-UTERINE DEVICES (IUDS)	KYLEENA	LEVONORGESTREL	17.5 mcg/24 hour (5 years)	New Strength
DRUGS TO TX CHRONIC INFLAMMATORY DISEASE OF COLON	INFLECTRA	INFLIXIMAB-DYYB	100 mg	New Entity

## NEW INDICATIONS (EXISTING DRUGS)

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### TECENTRIQ®

**October 18, 2016**

Genentech announced that the U.S. Food and Drug Administration (FDA) approved TECENTRIQ® (atezolizumab) for the treatment of people with metastatic non-small cell lung cancer (NSCLC) who have disease progression during or following platinum-containing chemotherapy, and have progressed on an appropriate FDA-approved targeted therapy if their tumor has EGFR or ALK gene abnormalities. This approval is based on results from the randomized Phase III OAK and Phase II POPLAR studies. The largest study, OAK, showed that TECENTRIQ helped people in the overall study population live a median of 13.8 months, 4.2 months longer than those treated with docetaxel chemotherapy (median overall survival [OS]: 13.8 vs. 9.6 months; HR = 0.74, 95% CI: 0.63, 0.87). The study enrolled people regardless of their PD-L1 status and included both squamous and non-squamous disease types.

Source: Genentech

### LUCENTIS®

**October 14, 2016**

Genentech announced that the U.S. Food and Drug Administration (FDA) approved the Lucentis® (ranibizumab injection) 0.5 mg prefilled syringe (PFS) as a new method of administering the medicine. Like the Lucentis 0.5 mg vial, the 0.5 mg PFS is approved to treat people with wet age-related macular degeneration (AMD) and macular edema after retinal vein occlusion (RVO). The Lucentis PFS is the first syringe prefilled with an anti-VEGF medicine FDA-approved to treat two eye conditions.

Source: Genentech

### Flublok® Quadrivalent Influenza Vaccine

**October 11, 2016**

Protein Sciences Corporation announced today that the FDA has approved its quadrivalent formulation of Flublok® influenza vaccine. Flublok Quadrivalent protects against 4 strains of influenza, 3 of the same strains found in trivalent Flublok plus an additional B strain. Significantly, Flublok Quadrivalent is the first and only high antigen content quadrivalent fluvaccine approved by FDA. It contains 3x more active ingredient than all other quadrivalent vaccines, making it a great choice for seniors and those with compromised immune systems, among others. In a clinical study of 9,000 adults 50 years of age and older, people who received Flublok Quadrivalent were over 40% less likely to get cell-culture confirmed influenza than those that received a leading egg-produced quadrivalent flu vaccine. These results are relevant for trivalent Flublok, as the H3N2 component of the vaccine that is shared between trivalent and Flublok Quadrivalent predominantly contributed to the improved efficacy.

Source: Protein Sciences Corporation



## **ORKAMBI®**

**September 28, 2016**

Vertex Pharmaceuticals Incorporated today announced that the U.S. Food and Drug Administration (FDA) approved ORKAMBI® (lumacaftor/ivacaftor) for use in children with cystic fibrosis (CF) ages 6 through 11 who have two copies of the F508del mutation. People with this mutation represent the largest population of those with CF, a rare, life-threatening disease. ORKAMBI is the first and only medicine to treat the underlying cause of CF for people with this mutation. It was previously approved by the FDA for use in people ages 12 and older with two copies of the F508del mutation. With today's approval, approximately 11,000 people with CF are eligible for treatment with ORKAMBI in the United States. ORKAMBI will be available for eligible children ages 6 through 11 in the United States as soon as possible. Vertex also today lowered its guidance for 2016 ORKAMBI revenues to a range of \$950 million to \$990 million.

Source: Vertex Pharmaceuticals Incorporated

## **STELARA®**

**September 26, 2016**

Janssen Biotech, Inc., announced today that the U.S. Food and Drug Administration (FDA) has approved STELARA® (ustekinumab) for the treatment of moderately to severely active Crohn's disease in adults (18 years or older) who have failed or were intolerant to treatment with immunomodulators or corticosteroids but never failed treatment with a tumor necrosis factor (TNF) blocker, or who failed or were intolerant to treatment with one or more TNF blockers. STELARA® is the first biologic therapy for Crohn's disease targeting interleukin (IL)-12 and IL-23 cytokines, which play a key role in inflammatory and immune responses.

Source: Janssen Biotech, Inc.

## **ILARIS®**

**September 23, 2016**

Novartis announced today that the US Food and Drug Administration (FDA) has granted three simultaneous approvals for the expanded use of Ilaris® (canakinumab) to treat three rare and distinct types of Periodic Fever Syndromes. Ilaris is the first and only FDA approved biologic treatment for Tumor Necrosis Factor- Receptor Associated Periodic Syndrome (TRAPS), Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD) and Familial Mediterranean Fever (FMF). All three conditions are part of a group of rare autoinflammatory diseases called Periodic Fever Syndromes, which are also referred to as Hereditary Periodic Fevers (HPF). The most common syndrome is FMF, which mainly affects people of Eastern Mediterranean ancestry. It affects 1 in 250 to 1 in 1,000 individuals in these populations, many of whom are children.

Source: Novartis

## FDA NEWS/BULLETINS/ADVISORIES/SAFETY ALERTS

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### Direct-Acting Antivirals for Hepatitis C: Drug Safety Communication - Risk of Hepatitis B Reactivating [10/4/2016]

**ISSUE:** The FDA is warning about the risk of hepatitis B virus (HBV) becoming an active infection again in any patient who has a current or previous infection with HBV and is treated with certain direct-acting antiviral (DAA) medicines for hepatitis C virus. In a few cases, HBV reactivation in patients treated with DAA medicines resulted in serious liver problems or death. HBV reactivation usually occurred within 4-8 weeks. As a result, FDA is requiring a Boxed Warning, our most prominent warning, about the risk of HBV reactivation to be added to the drug labels of these DAAs directing health care professionals to screen and monitor for HBV in all patients receiving DAA treatment. This warning will also be included in the patient information leaflet or Medication Guides for these Medicines.

**BACKGROUND:** Direct-acting antiviral medicines are used to treat chronic hepatitis C virus (HCV) infection, an infection that can last a lifetime. These medicines reduce the amount of HCV in the body by preventing HCV from multiplying, and in most cases, they cure HCV. Without treatment, HCV can lead to serious liver problems including cirrhosis, liver cancer, and death (see List of Direct-Acting Antivirals in the FDA Drug Safety Communication). FDA identified 24 cases of HBV reactivation reported to FDA and from the published literature in HCV/HBV co-infected patients treated with DAAs during the 31 months from November 22, 2013 to July 18, 2016. This number includes only cases submitted to FDA, so there are likely additional cases about which FDA is unaware. Of the cases reported, two patients died and one required a liver transplant. HBV reactivation was not reported as an adverse event in the clinical trials submitted for the DAA approvals because patients with HBV co-infection were excluded from the trials. See the data summary section in the Drug Safety Communication for more detailed information.

**RECOMMENDATION:** Health care professionals should screen all patients for evidence of current or prior HBV infection before starting treatment with DAAs, and monitor patients using blood tests for HBV flare-ups or reactivation during treatment and post-treatment follow-up.

Patients should tell your health care professional if you have a history of hepatitis B infection or other liver problems before being treated for hepatitis C. Do not stop taking your DAA medicine without first talking to your health care professional. Stopping treatment early could result in your virus becoming less responsive to certain hepatitis C medicines. Read the patient information leaflet or Medication Guide that comes with each new prescription because the information may have changed. Contact your health care professional immediately if you develop fatigue, weakness, loss of appetite, nausea and vomiting, yellow eyes or skin, or light-colored stools, as these may be signs of serious liver problems. Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: [www.fda.gov/MedWatch/report](http://www.fda.gov/MedWatch/report)
- Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

Source: U.S. Food and Drug Administration

## Hyoscyamine sulfate 0.125mg by Virtus Pharmaceuticals: Recall - Superpotent and Subpotent Test Results

[9/15/2016]

**ISSUE:** Virtus Pharmaceuticals Opco II, LLC (Virtus) is voluntarily recalling seven batches of Hyoscyamine sulfate (0.125mg) to the consumer level which include the tablet, sublingual, and orally disintegrating tablet form. This recall is being initiated due to both superpotent and subpotent test results. All of these batches were manufactured by Pharmatech LLC for distribution by Virtus throughout the United States and Puerto Rico. See the press release for a listing of affected batch numbers. Taking a product that is superpotent could result in hot/dry skin, fever, blurred vision, sensitivity to light, dry mouth, unusual excitement, fast or irregular heartbeat, dizziness, an inability to completely empty the bladder, and seizures. The severity of the adverse event would depend on how superpotent the tablet was. Adverse events such as clotted blood within the tissues and fractures could occur, as a result of falls from dizziness or seizures if the strength is particularly high. To date, Virtus has received three adverse event reports involving hallucinations, stroke-like symptoms, confusion, dizziness, blurred vision, dry mouth, slurred speech, imbalance, and disorientation.

**BACKGROUND:** Hyoscyamine sulfate is an anticholinergic agent which blocks the action of acetylcholine and is used to treat diseases like asthma, incontinence, stomach cramps, peptic ulcers, control gastric secretion, intestinal spasm and other bowel disturbances. These products were distributed Nationwide in the U.S. and Puerto Rico starting on March 11, 2016, to distributors, hospitals, and retail pharmacies.

**RECOMMENDATION:** Virtus is notifying its distributors and retailers by letter and email and is arranging for return of all recalled drug product. Consumers, distributors, and retailers that have the hyoscyamine sulfate product lots listed above should stop using/distributing and return to place of purchase. Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: [www.fda.gov/MedWatch/report](http://www.fda.gov/MedWatch/report)
- Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

Source: U.S. Food and Drug Administration

## STUDIES and RECENT TOPICS

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### Preteens need only 2 HPV shots, not 3, CDC says

**October 19, 2016**

It's now easier for preteens to get the cervical cancer vaccine. The government on Wednesday quickly adopted a recommendation that preteens get two shots instead of three and space them further apart. Health officials hope that will boost the number of girls and boys who get vaccinated.

Source: yahoo.com

### Prostate cancer hormone therapy tied to higher dementia risk

**October 18, 2016**

Men who take hormone therapy for prostate cancer may have a higher risk of dementia than patients who receive different treatment for these malignancies, a U.S. study suggests. Prostate cancer cells need testosterone to grow and spread. Researchers focused on a common treatment known as androgen deprivation therapy (ADT), which works by depriving tumor cells of testosterone. Side effects can include sexual dysfunction, weight gain and fatigue.

Source: reuters.com

### Statins Often Interact With Other Heart Drugs

**October 17, 2016**

Cholesterol-lowering statins can interact with other drugs prescribed for heart disease. But there are ways to navigate the problem, according to new recommendations from the American Heart Association. Statins are among the mostly widely prescribed drugs in the United States. Roughly onequarter of Americans age 40 and up are on a statin, according to a 2014 study by the U.S Centers for Disease Control and Prevention.

Source: realclearhealth.com

### Study links antidepressants in pregnancy with language disorders

**October 12, 2016**

Selective serotonin reuptake inhibitors, known as SSRIs, are the most common type of antidepressants prescribed to pregnant women. Yet a new study indicates that when taken during pregnancy, the drugs are associated with a higher risk of language disorders, including dyslexia, in offspring.

Source: cnn.com

### **FDA clears Xarelto blood thinner despite faulty trial device**

**October 11, 2016**

The U.S. Food and Drug Administration on Tuesday said it has determined the widely-used blood thinner Xarelto to be safe and effective for patients with the heart condition atrial fibrillation after serious doubts arose over the major study used to gain approval of the drug.

Source: reuters.com

### **High blood pressure drugs impact depression, bipolar disorder**

**October 11, 2016**

Depression and cardiovascular disease are major contributors to the global burden of disease. A bidirectional relationship is thought to exist between depression and heart disease due to the functional changes that underlie both conditions. Bipolar disorder is associated with an increased risk of cardiovascular mortality and high blood pressure, whereas major depressive disorder is associated with an increased risk of high blood pressure.

Source: medicalnewstoday.com

### **Botox shots little better than nerve stimulation for incontinence**

**October 4, 2016**

Botox injections may be slightly better at reducing urinary incontinence in some older women than InterStim, an implanted bladder control device, results of a U.S. trial suggest. Researchers tested onabotulinumtoxinA (Botox) against InterStim in patients with overactive bladder who couldn't tolerate or didn't respond to other drugs or treatments such as pelvic floor muscle training or fluid restriction.

Source: reuters.com

### **Some Increased Bleeding Risk Seen With Blood Thinner Xarelto Vs. Pradaxa**

**October 3, 2016**

The blood thinner Xarelto may pose a slightly greater risk of serious bleeding than Pradaxa in patients with the abnormal heartbeat known as atrial fibrillation, new research suggests. Most patients with the condition take a blood thinner to reduce the risk of stroke. Although these drugs help prevent stroke, they can also cause uncontrollable bleeding, which can be fatal, the researchers said.

Source: healthday.com

### **HPV Vaccine More Effective Than Thought: Study**

**September 29, 2016**

The vaccine against human papillomavirus (HPV) infection, which doctors believe causes most cases of cervical cancer, appears even more effective than believed, a new study finds. "After eight years of

vaccination, the reduction in the incidence of cervical neoplasia [abnormal growth of cells], including pre-cancers, have been reduced approximately 50 percent. This is greater than what was expected -- that's pretty exciting," said lead researcher Cosette Wheeler. She is a professor of pathology and obstetrics and gynecology at the University of New Mexico, in Albuquerque.

Source: healthday.com

### **Popular Painkillers Like Ibuprofen Are Linked to Heart Problems** **September 28, 2016**

Painkillers can be both a blessing and a curse. They're effective at numbing everything from the inflammation that comes with infection to headaches and the achy joints of arthritis. But recent studies have exposed some serious side effects, including increased risk of heart events. The newest class of these drugs, COX-2 inhibitors, seemed especially risky for the heart, leading to the withdrawal from the market of one medication and a Food and Drug Administration warning on others.

Source: time.com

### **Statins Linked to Improved Overall Survival in Multiple Myeloma** **September 21, 2016**

In a large cohort of US veterans with multiple myeloma, statin therapy was associated with a decreased risk of all-cause and cancer-specific mortality, according to a study published in the Journal of Clinical Oncology. Statins are active in 1 of the pathways affected by nitrogen-containing bisphosphonates, which have been linked to prolonged survival among patients with multiple myeloma. Researchers evaluated the association between statin use and mortality in a cohort of patients with myeloma.

Source: cancertherapyadvisor.com

### **Prescription painkillers are more widely used than tobacco, new federal study finds** **September 20, 2016**

More than 1 in 3 American adults -- 35 percent -- were given painkiller prescriptions by medical providers last year. The total rate of painkiller use is even higher -- 38 percent -- when you factor in the number of adults who obtained painkillers for misuse via other means, from friends or relatives, or via drug dealers.

Source: washingtonpost.com

### **Amgen cholesterol drug reduces arterial plaque buildup: study** **September 20, 2016**

Amgen said on Tuesday its potent new cholesterol fighter, Repatha, met the primary and secondary goals of a study designed to show it can decrease plaque buildup in heart arteries of patients already

taking widely used statin drugs, such as Lipitor. The biotechnology company, whose shares were up 1.6 percent, will present detailed data from the study at a major heart conference in November.

Source: reuters.com

### **Amgen-UCB bone drug cuts fractures in osteoporosis for older women** **September 19, 2016**

New data for Amgen and UCB's bone drug romosozumab (aka romo) showed it could help lower certain fractures in older women as it awaits an FDA approval decision next year. In new figures posted in The New England Journal of Medicine, the two companies said their co-developed experimental med romo "significantly reduced the incidence of vertebral fractures in postmenopausal women with osteoporosis" through one and two years, hitting its co-primary endpoints.

Source: fiercebiotech.com

### **Novartis intensifies Entresto push with new analysis** **September 19, 2016**

Novartis on Monday intensified its bid to convince doctors to prescribe its heart failure drug Entresto, releasing an analysis that concluded the medicine contributed to higher quality of life scores compared with an older drug. The decline in health-related quality of life scores among patients hospitalized with reduced ejection fraction heart failure was less steep among Entresto patients compared to those taking the drug enalapril, Switzerland's Novartis said in a statement.

Source: reuters.com

### **Biosimilars Face Repercussions of Drug Pricing Debate** **September 18, 2016**

As more biosimilars gain FDA approval for marketing in the U.S., and more manufacturers launch programs to develop additional competitive biotech therapies, concerns have emerged that continued growth in this area could be limited by mounting pressure to push down on prescription drug outlays. Even though payers and insurers anticipate savings from alternative biotech therapies, the threat is that aggressive cost-cutting measures could raise the demand for truncated biosimilar development, eroding the confidence of physicians and patients about biosimilar safety and efficacy.

Source: pharmexec.com

## RECALLS

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
Drugs	DOBUtamine Injection, USP 250 mg/20 mL, 20 mL Vial, For IV Use Only, Must be Diluted Prior to Use, (12.5 mg per mL), Rx Only, Hospira, Inc., Lake Forest, IL 60045 USA, NDC 0409-2025-20	Class II	Lot #: 52175DD, Exp 01 Oct 2016	Discoloration: Firm received complaints of product discoloration and particulates.	Hospira Inc. 275 N Field Dr Lake Forest, IL 60045-2579
Drugs	Pantoprazole Sodium Delayed-Release Tablets USP, 40 mg Rx Only, 90 tablets per bottle, Manufactured for Aurobindo Pharma USA, Inc 2400 Route 130 North Dayton, NJ 08810, Manufactured by: Aurobindo Pharma Limited Unit-VII (SE2), Mahaboob Nagar (Dt) - 509302, India , NDC 65862-0560-90	Class II	PSSB16011-A, Exp 01/18	Presence of Foreign Tablets/Capsules: Firm received a market complaint stating the presence of one foreign tablet (Montelukast Sodium Chewable Tab 4mg) in the product bottle of Pantoprazole.	Aurobindo Pharma USA Inc 666 Plainsboro Rd Ste 210 Plainsboro, NJ 08536-3004
Drugs	buPROPion Hydrochloride Extended-Release Tablets, USP (XL), 300mg, 500-count bottle, Rx only, Manufactured by: Cadila Healthcare Ltd., Ahmedabad, India For BluePoint Laboratories, NDC 68001-264-03	Class III	Lot #: MS1509, Exp 12/17	Failed dissolution specifications - the out of specification result for dissolution was identified during 3 month stability testing.	Amerisource Health Services 2550 John Glenn Ave Ste A Columbus, OH 43217-1188
Drugs	Carvediol Tablets, USP, 3.125 mg, 100-count bottle (NDC 57664-242-88). 500-count bottle (NDC 57664-242-13), 1000-count bottle (NDC 57664-242-18), Rx Only Manufactured by: ALKALOIDA Chemical Company Zrt 440 Tisavasvari Kabay Janos u. 29 Hungary, Distributed by Sun Pharmaceutical Industries, Inc. Cranbury, NJ 08512	Class III	Lot #: AVF0246/A, AVF0247/B, AVF0246/B, AVF0246/C; Exp. 02/17	Failed Impurities/Degradation Specifications	Sun Pharmaceutical Industries, Inc. 270 Prospect Plains Rd Cranbury, NJ 08512-3605
Drugs	Carvediol Tablets, USP, 6.25 mg, 100-count bottle (NDC 57664-244-18), 500-count bottle (NDC 57664-244-13), 1000-count bottle (NDC 57664-244-18), Rx Only, Manufactured by: ALKALOIDA Chemical Company Zrt 440 Tisavasvari Kabay Janos u. 29 Hungary, Distributed by Sun Pharmaceutical Industries, Inc. Cranbury, NJ 08512	Class III	Lot #: AVF0254/C, AVF0254/B, AVF0254/C; Exp. 02/17	Failed Impurities/Degradation Specifications	Sun Pharmaceutical Industries, Inc. 270 Prospect Plains Rd Cranbury, NJ 08512-3605
Drugs	Carvediol Tablets, USP, 12.5 mg, 500-count bottle (NDC	Class III	Lot #: AVF0256/A , AVF0256/B, AVF0256/C; Exp. 02/17	Failed Impurities/Degradation	Sun Pharmaceutical



Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
	57664-245-13), 1000-count bottle (NDC 57664-245-18), Rx Only Manufactured by: ALKALOIDA Chemical Company Zrt 440 Tisavasvari Kabay Janos u. 29 Hungary, Distributed by Sun Pharmaceutical Industries, Inc. Cranbury, NJ 08512			Specifications	Industries, Inc. 270 Prospect Plains Rd Cranbury, NJ 08512-3605
Drugs	Carvediol Tablets, USP, 25 mg, 100-count bottle (NDC 57664-247-88), 500-count bottle (NDC 57664-247-13), 1000-count bottle (NDC 57664-247-18), Rx Only Manufactured by: ALKALOIDA Chemical Company Zrt 440 Tisavasvari Kabay Janos u. 29 Hungary, Distributed by: Sun Pharmaceutical Industries, Inc. Cranbury, NJ 08512	Class III	Lot # AVF0258/A, AVF0258/B, AVF0258/C, AVF0259/A, AVF0259/C; Exp. 02/17	Failed Impurities/Degradation Specifications	Sun Pharmaceutical Industries, Inc. 270 Prospect Plains Rd Cranbury, NJ 08512-3605
Drugs	Escitalopram Tablets USP 20 mg, 100-count bottles, Rx Only, Manufactured for: Lupin Pharmaceuticals, Baltimore, MD, 21202, Manufactured by: Lupin Limited, Goa 403 722, India, NDC 68180-136-01	Class III	Lot # G510086; Exp. 11/17	Labeling: Incorrect or Missing Lot and/or Expiration Date	Lupin Limited 15-B, Phase 1A, Verna Industrial Area Verna, Salcette, Goa
Drugs	Lisinopril Tablets USP, 30 mg, packaged in a) 500-count bottles (NDC 68180-516-02) and b) 100-count bottles (NDC 68180-516-01); Rx only, Manufactured for: Lupin Pharmaceuticals, Inc., Baltimore, MD 21202, United States; Manufactured by: Lupin Limited, Pithampur (M.P.) 454 775, INDIA.	Class III	Batch number: H303487, H303488, H303489, Exp 09/16	CGMP Deviations: finished products manufactured using active pharmaceutical ingredients whose intermediates failed specifications.	Lupin Pharmaceuticals Inc. 111 S Calvert St Fl 21ST Baltimore, MD 21202-6174
Drugs	Mucinex Sinus-Max Day Night, 60 caplets, Dist. by Reckitt Benckiser, Parsippany, NJ 07054-0224 UPC 363824951737 NDC 63824-207-60	Class III	WO00809739, 9/2017	Labeling: Label Error on Declared Strength; label on outer carton incorrectly states Diphenhydramine 25 mg instead of 12.5 mg. Also, quantity is incorrectly stated as 30 daytime and 30 nighttime instead of 36 daytime and 24 nighttime.	Reckitt Benckiser LLC 399 Interpace Pkwy Parsippany, NJ 07054-1133
Drugs	Mozobil (plerixafor injection) 24 mg/1.2 mL (20 mg/mL) per vial, Rx Only, For Subcutaneous Injection only, Manufactured by: Genzyme Corporation, 500 Kendall Street, Cambridge, MA 02142 A Sanofi Company Country of Origin : United Kingdom, NDC 0024-5862-01	Class III	Lot # 5RZ002; Exp. 04/18	Labeling: Incorrect or Missing Lot and/or Exp. Date	Genzyme Corporation / Genzyme Biosurgery 1125 Pleasantview Ter Ridgefield, NJ 07657-2310

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
Drugs	Ephedrine Sulfate Injection, USP, 50 mg/mL, 1 mL Fill in a 2mL Vial (NDC 66758-008-01), packaged in 25 x 2 mL Vials per carton (NDC 66758-008-02), Rx only, Manufactured for: Sandoz Inc., Princeton, NJ 08540.	Class II	Lot #: 080514, 080614, 081114, 081214, 081314, 081414, 082714, 082814, 082914, Exp 08/16; 090214, 090314, 090814, 090914, 091014, 091114, 091214, 091514, Exp 09/16	Lack of Assurance of Sterility: a recent FDA inspection at the manufacturing firm raised concerns that product sterility may be compromised.	Sandoz Inc 100 College Rd W Princeton, NJ 08540-6604
Drugs	Phenylephrine HCl Injection, USP, 10mg/mL, packaged in a) 5 mL Vial, 50 mg/5 mL (NDC 66758-016-03), 25 x 5 mL Vials per carton (NDC 66758-016-04) and b) 10 mL Vials, 100 mg/10 mL (NDC 66758-017-01), Rx only, Manufactured for: Sandoz Inc., Princeton, NJ 08540.	Class II	Lot #: a) 091914, Exp 09/16; b) 080114, Exp 08/16; 090414, 092614, Exp 09/16	Lack of Assurance of Sterility: a recent FDA inspection at the manufacturing firm raised concerns that product sterility may be compromised.	Sandoz Inc 100 College Rd W Princeton, NJ 08540-6604
Drugs	Amoxicillin For Oral Suspension, USP - Dye Free, 400 mg/5 mL, 100 mL (when reconstituted), Rx only, Manufactured by: Hikma Pharmaceuticals, PO Box 182400, Amman 11118 - Jordan, Distributed by: West-Ward Pharmaceutical Corp. Eatontown, NJ 07724, NDC 00143-9887-01,	Class III	Lot #: AS1413A, AS1414A; Exp. 11/18	Labeling: Label Error on Declared Strength- bottles missing colored coded panel where strength of the product is displayed.	West-Ward Pharmaceuticals Corp. 401 Industrial Way West Eatontown, NJ 07724-2209
Drugs	Lisinopril Tablets USP, 40 mg, 1000-count bottles, Rx only, Manufactured for: Lupin Pharmaceuticals, Inc., Baltimore, MD 21202, United States; Manufactured by: Lupin Limited, Pithampur (M.P.) 454 775, INDIA, NDC 68180-517-03.	Class III	Batch number: H303449, Exp 09/16	CGMP Deviations: finished products manufactured using active pharmaceutical ingredients whose intermediates failed specifications.	Lupin Pharmaceuticals Inc. 111 S Calvert St Fl 21ST Baltimore, MD 21202-6174
Drugs	Sennazon (sennosides) Syrup, 8.8 mg, 8 fl. oz. (237 mL) bottle, Mfd. for: Bayshore Pharmaceuticals, Tampla, FL 33619, NDC 76518-100-08.	Class II	Lot #: 20391519, Exp 11/17	CGMP Deviations: Recall initiated as a precautionary measure due to a potential risk of product contamination with the bacteria B. cepacia.	Pharmatech LLC 4131 Sw 47th Ave Suite 1403 Davie, FL 33314- 4026
Drugs	Ninjacof-A (acetaminophen, chlorphedianol HCl, pyrilamine maleate) Liquid, 160 mg/12.5 mg/12.5 mg in each 5 mL, 16 fl oz (473 mL) bottle, Manufactured for: Centurion Labs, LLC, Birmingham, AL 35243, NDC 23359-033-16.	Class II	Lot #: 25291601, Exp 04/18	CGMP Deviations: Recall initiated as a precautionary measure due to a potential risk of product contamination with the bacteria B. cepacia.	Pharmatech LLC 4131 Sw 47th Ave Suite 1403 Davie, FL 33314- 4026
Drugs	Aller-Chlor (chlorpheniramine maleate) Syrup, USP, 2 mg in each 5 mL, 4 fl oz (120 mL) bottle, Distributed by: Rugby Laboratories, 31778 Enterprise Drive, Livonia, MI 48150, NDC	Class II	Lot #: 23261501, Exp 10/17	CGMP Deviations: Recall initiated as a precautionary measure due to a potential risk of product contamination with the bacteria B. cepacia.	Pharmatech LLC 4131 Sw 47th Ave Suite 1403 Davie, FL 33314- 4026

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
	0536-1025-47.				
Drugs	Diocto Syrup (docusate sodium), 60 mg/15 mL, One Pint (473 mL) bottle, Dist. by: Rugby Laboratories, 31778 Enterprise Drive, Livonia, MI 48150, NDC 0536-1001-85.	Class II	Lot #: 22941505, Exp 10/17; 229416601, Exp 01/18; 22941602, Exp 03/18	CGMP Deviations: Recall initiated as a precautionary measure due to a potential risk of product contamination with the bacteria B. cepacia.	Pharmatech LLC 4131 Sw 47th Ave Suite 1403 Davie, FL 33314-4026
Drugs	Senexon Liquid (sennosides) 8.8 mg, 8 fl. oz. (237 mL) bottle, Distributed by: Rugby Laboratories, 31778 Enterprise Drive, Livonia, MI 48150, NDC 0536-1000-59.	Class II	Lot #: 20391515, 20391516, Exp 08/17; 20391517, Exp 09/17; 20391518, Exp 10/17; 20391520, Exp 11/17; 20391521, Exp 12/17; 20391601, Exp 01/18; 20391603, 20391604, Exp 03/18; 20391606, 20391607, Exp 04/18; 20391609, Exp 06/18.	CGMP Deviations: Recall initiated as a precautionary measure due to a potential risk of product contamination with the bacteria B. cepacia.	Pharmatech LLC 4131 Sw 47th Ave Suite 1403 Davie, FL 33314-4026
Drugs	Senna Syrup (sennosides) 8.8 mg, 8 fl. oz. (237 mL) bottle, Distributed by: Major Pharmaceuticals, 31778 Enterprise Drive, Livonia, MI 48150, NDC 0904-6289-09.	Class II	Lot #: 20391517, Exp 09/17; 20391518, Exp 10/17; 20391519, Exp 11/17; 20391601, Exp 01/18; 20391602, Exp 02/18; 20391604, 20391605, Exp 03/18; 20391608, Exp 06/18	CGMP Deviations: Recall initiated as a precautionary measure due to a potential risk of product contamination with the bacteria B. cepacia.	Pharmatech LLC 4131 Sw 47th Ave Suite 1403 Davie, FL 33314-4026
Drugs	Lansoprazole Delayed-Release Capsules, USP, 30 mg, packaged in 100-count cartons of 10 x 10 unit dose blister cards, Rx only, Manufactured by: Dr. Reddy's Laboratories, Inc., 200 Somerset Corporate Blvd Floor 7, Bridgewater, NJ 08807, NDC 63739-0555-10	Class III	Lot # 0111295, Exp 9/17	Labeling: Label mix-up. The inner packaging was properly labeled Omeprazole DR 40mg Capsules, but the outer secondary packaging was mislabeled Lansoprazole Delayed-Release 30mg Capsules.	Mckesson Packaging Services 7101 Weddington Rd NW Concord, NC 28027-3412
Drugs	Chlorpheniramine Maleate 10 mg/ml, 30 ml MDV, Rx, Vital Care Compounder, Hattiesburg, MS 39402	Class II	Lot# 373003, 381408, Use by 02-11-17	Lack of Assurance of Sterility	Pharmacy Plus, Inc. dba Vital Care Compounder 115 S 40th Ave Hattiesburg, MS 39402-6600
Drugs	Buprenorphine, 0.6 mg/ml Injection, 20ml MDV Sterile, Rx, Vital Care Compounder, Hattiesburg, MS	Class II	Lot# 396691, Use by 09-13-16	Lack of Assurance of Sterility	Pharmacy Plus, Inc. dba Vital Care Compounder 115 S 40th Ave Hattiesburg, MS 39402-6600
Drugs	Apomorphine HCl 3mg/ml Sterile Injection Solution, 10 mL, MDV, Rx, Vital Care Compounder, Hattiesburg, MS	Class II	Lot# 397876, Use by 10-27-16	Lack of Assurance of Sterility	Pharmacy Plus, Inc. dba Vital Care Compounder 115 S 40th Ave Hattiesburg, MS 39402-6600
Drugs	Moxifloxacin 0.5% +	Class	Lot# 396627, Use by 8-10-16	Lack of Assurance of	Pharmacy Plus,

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
	Dexamethazone 0.1%, 15ml vial Contains: Moxifloxacin 5mg/ml, Dexamethasone Sodium Phosphate 1mg/ml, Rx only, For ophthalmic use only, Vital Care Compounder, Hattiesburg, MS	II		Sterility	Inc. dba Vital Care Compounder 115 S 40th Ave Hattiesburg, MS 39402-6600
Drugs	MOXI/DEX/KETOROLAC 0.5%/0.1%/0.4%, #15, Vital Care Compounder, Hattiesburg, MS 39402	Class II	Lot#: 399080, Use by 8-14-16; 399740, Use by 8-25-16; 398952, Use by 8-13-16; 398865, Use by 8-11-16; 399057, Use by 8-13-16; 398864, Use by 8-11-16	Lack of Assurance of Sterility	Pharmacy Plus, Inc. dba Vital Care Compounder 115 S 40th Ave Hattiesburg, MS 39402-6600
Drugs	Papaverine 150 mg / Phentolamine 5 mg vials, packaged 5.5 mL in a sterile, clear 10 mL MDV, Rx only, Sterile Injection, Vital Care Compounder, Hattiesburg, MS 39402	Class II	Lot# 386184, Use by 08-03-16	Lack of Assurance of Sterility	Pharmacy Plus, Inc. dba Vital Care Compounder 115 S 40th Ave Hattiesburg, MS 39402-6600
Drugs	Trypan Blue 0.3%, 0.5ml vials, Rx, Vital Care Compounder, Hattiesburg, MS 39402	Class II	Lot# 396770, Use by 09-13-16	Lack of Assurance of Sterility	Pharmacy Plus, Inc. dba Vital Care Compounder 115 S 40th Ave Hattiesburg, MS 39402-6600
Drugs	Brilliant Blue G (BBG) 0.025%, 0.5 ml SDV, Rx, Vital Care Compounder, Hattiesburg, MS 39402	Class II	Lot# 396817, Use by 09/13/16	Lack of Assurance of Sterility	Pharmacy Plus, Inc. dba Vital Care Compounder 115 S 40th Ave Hattiesburg, MS 39402-6600
Drugs	Moxifloxacin HCl 1 mg/ml (0.1mg/0.1ml) and BSS solution, 2ml Single use vial, Rx, Vital Care Compounder, Hattiesburg, MS 39402	Class II	Lot# 396607, Use by 08/13/16	Lack of Assurance of Sterility	Pharmacy Plus, Inc. dba Vital Care Compounder 115 S 40th Ave Hattiesburg, MS 39402-6600
Drugs	Morphine Sulfate 15mg/ml Injection, 20 ml MDV, Rx, Vital Care Compounder, Hattiesburg, MS	Class II	Lot# 396689, Use by 12-13-16	Lack of Assurance of Sterility	Pharmacy Plus, Inc. dba Vital Care Compounder 115 S 40th Ave Hattiesburg, MS 39402-6600
Drugs	Methylcobalamin 5,000mcg/ml, 1mL SDV, Rx, Vital Care Compounder, Hattiesburg, MS 39402	Class II	Lot# 396814, Use by 12-14-16	Lack of Assurance of Sterility	Pharmacy Plus, Inc. dba Vital Care Compounder

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
					115 S 40th Ave Hattiesburg, MS 39402-6600
Drugs	Autologous Serum Tears, 2 vials, Rx, Vital Care Compounder, Hattiesburg, MS 39402	Class II	Lot#: 390325, Use by 08/01/16; 382789, Use by 08/07/16; 396766, Use by 08/11/16; 393470, Use by 08/14/16; 393036, Use by 08/14/16; 398131, Use by 08/15/16; 389288, Use by 08/20/16; 392969, Use by 08/21/16	Lack of Assurance of Sterility	Pharmacy Plus, Inc. dba Vital Care Compounder 115 S 40th Ave Hattiesburg, MS 39402-6600
Drugs	Pre-Op Pledget Soln, Ophthalmic Drops (Tropicamide (1%) 0.33ml, Phenylephrine (10%) 0.66ml, Ketorolac (0.5%) 0.33ml, Ofloxacin (0.3) 0.67ml, 2ml vial, Rx, Vital Care Compounder, Hattiesburg, MS	Class II	Lot# 397267, Use by 9/20/16	Lack of Assurance of Sterility	Pharmacy Plus, Inc. dba Vital Care Compounder 115 S 40th Ave Hattiesburg, MS 39402-6600
Drugs	Hydroxyzine HCl, 50mg/ml Inj, 10ml MDV, Rx, Vital Care Compounder, Hattiesburg, MS	Class II	Lot #: 365204, Use by 8/1/16 and 384395, Use by 3/12/17	Lack of Assurance of Sterility	Pharmacy Plus, Inc. dba Vital Care Compounder 115 S 40th Ave Hattiesburg, MS 39402-6600
Drugs	C-PAP/PHEN/PROST/ATROP 150/5/5 (Papaverine 150mg/Phentolamine 5mg/Prostaglandin 50mcg/Atropine 0.04mg injection), Rx, 10 ml vials contain 5.8 ml solution, Vital Care COMPOUNDER, Hattiesburg, MS 39402	Class II	Lot# 397877, USE BY 1-6-17	Lack of Assurance of Sterility	Pharmacy Plus, Inc. dba Vital Care Compounder 115 S 40th Ave Hattiesburg, MS 39402-6600
Drugs	Olopatadine 0.8% Ophthalmic Solution, 3ml bottle, Rx, Vital Care Compounder, Hattiesburg, MS	Class II	Lot# 389278, Use by 8-9-16	Lack of Assurance of Sterility	Pharmacy Plus, Inc. dba Vital Care Compounder 115 S 40th Ave Hattiesburg, MS 39402-6600
Drugs	C-PAP/PHEN/PROST/Atrop 150/7.5 (Papaverine 150mg/Phentolamine 7.5mg/Prostaglandin 75mcg/Atropine 1mg injection), 10 ml vial containing 5.9ml solution, Rx, Vital Care Compounder, Hattiesburg, MS	Class II	Lot# 397877, USE BY 1-6-17	Lack of Assurance of Sterility	Pharmacy Plus, Inc. dba Vital Care Compounder 115 S 40th Ave Hattiesburg, MS 39402-6600
Drugs	Hyaluronidase, 150 u/ml, 10 ml SDV, Vital Care Compounder, Hattiesburg, MS 39402	Class II	Lot# 398178, Use by 12/30/16	Lack of Assurance of Sterility	Pharmacy Plus, Inc. dba Vital Care Compounder

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
					115 S 40th Ave Hattiesburg, MS 39402-6600
Drugs	DMSO 50% with Lidocaine 0.5%, 50ml SDV, Sterile, Rx, Vital Care Compounder, Hattiesburg, MS	Class II	Lot # 389321, Use by 3/10/17	Lack of Assurance of Sterility	Pharmacy Plus, Inc. dba Vital Care Compounder 115 S 40th Ave Hattiesburg, MS 39402-6600
Drugs	Lamotrigine Tablets, USP, 150 mg, 500-count Tablets per bottle, Rx only, Manufactured by: Unichem Laboratories LTD., Pilerne Ind. Estate, Pilerne, Bardez, Goa 403 511 India; Marketed by: Unichem Pharmaceuticals (USA), Inc., Rochelle Park, NJ 07662; NDC 29300-113-05.	Class III	Lot #: GLEH 16003, Exp 03/31/18	Tablets/Capsules Imprinted With Wrong ID: incorrect imprint debossed on the tablets.	Unichem Pharmaceuticals Usa Inc 777 Terrace Ave Suite 102 Hasbrouck Heights, NJ 07604-3102
Drugs	Xanax (Alprazolam) USP, CIV, 0.5 mg tablets, 10 x 10 blister cards per carton, Rx Only, Manufactured by Sandoz Inc., Princeton, NJ 08805, NDC 63739-669-10	Class III	Lot #: 0111512; Exp. 08/17	Labeling: Missing Label-Primary packaging label (i.e. blister card) is blank and contains no product information (e.g. product name, strength, lot number, expiry).	Mckesson Packaging Services 7101 Weddington Rd NW Concord, NC 28027-3412
Drugs	PREMARIN (conjugated estrogen tablets, USP) 1.25 mg, 1000- count bottle, Rx only, Distributed by: Wyeth Pharmaceuticals Inc. A subsidiary of Pfizer Inc. Philadelphia, PA 19101, NDC 0046-1104-91	Class III	Lot # M35953S; Exp. 11/17 (labeled).	Labeling: Incorrect or Missing Lot and/or Exp Date: Bottles were incorrectly labeled with an expiry date of 11/17; the correct date is 09/17.	Pfizer Inc. 235 East 42nd Street New York, NY 10017-5703
Drugs	Claravis (isotretinoin capsules USP), 10mg, packaged in carton containing 3 Blister Packs of 10 Capsules Each (30 Capsules total); Rx only, TEVA PHARMACEUTICALS USA, Sellersville, PA 18960. NDC 00555-1054-86	Class III	Lot #: 34025714A, Exp. Date 12/2016	Failed Impurities/Degradation Specifications.	Teva North America 425 Privet Rd Horsham, PA 19044-1220
Drugs	Vyvanse (lisdexamfetamine dimesylate) Capsules 30 mg, 100 count bottle, Rx Only, Manufactured for: Shire US, Inc., Lexington, MA 02421, NDC 59417-103-10	Class III	Lot # AF3360B; Exp. 04/19	Presence of Foreign Tablets/Capsules	Shire 1200 Morris Dr Chesterbrook, PA 19087-5507
Drugs	Methylcobalamin 5000 mcg/mL Injection, packaged in 1, 2, 3, 4, and 5 mL vials, IM,	Class II	071222016@24 BUD 01/08/2017, 05112016@8 BUD 11/07/2016	Lack of Assurance of Sterility; medication was sterilized with a recalled	The Apothecary Shoppe LLC 6136 E 51st St

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
	Rx, The Apothecary Shoppe Compounding Pharmacy, Jenks, OK			filter	Tulsa, OK 74135-7704
Drugs	Phentolamine 0.4mg/Prostaglandin 20mcg/mL packaged in 2.5 mL sterile vials, IM, Rx, The Apothecary Shoppe, Jenks, OK	Class II	05162016@18 BUD 09/13/2016; 07052016@9 BUD 11/02/2016; 08032016@13 BUD 12/01/2016	Lack of Assurance of Sterility; medication was sterilized with a recalled filter	The Apothecary Shoppe LLC 6136 E 51st St Tulsa, OK 74135-7704
Drugs	Tri-Mix 18/1/10 (Papaverine 18mg, Phentolamine 1 mg, Prostaglandin 10 mcg/mL) packaged in 2.5 mL sterile vials, IM, Rx, The Apothecary Shoppe, Jenks, OK	Class II	07252016@22 BUD 09/22/2016; 08102016@28 BUD 10/08/2016	Lack of Assurance of Sterility; medication was sterilized with a recalled filter	The Apothecary Shoppe LLC 6136 E 51st St Tulsa, OK 74135-7704
Drugs	buPROPion Hydrochloride Extended-release Tablets, USP (SR), 150 mg, Twice-A-Day, in 60 count bottles, Rx only, Distributed by: Sun Pharmaceutical Industries, Inc. Cranbury, NJ 08512 Manufactured by Sun Pharmaceuticals Ind. Ltd. Halol-Baroda Highway, Halol-389 350, Gujarat, India. UPC 347335737868 NDC 47335-737-86	Class III	JKN5124A and JKN5229A, exp 10/2016	Failed Dissolution Specifications	Sun Pharmaceutical Industries, Inc. 270 Prospect Plains Rd Cranbury, NJ 08512-3605
Drugs	PredniSONE Tablets USP, 1 mg, 100-count bottles, Rx only, Distr. by: West-Ward Pharmaceuticals Corp., Eatontown, NJ 07724, NDC 0054-4741-25.	Class II	Lot # 660621A, Exp 01/31/18	Failed Tablet/Capsule Specifications: Discovery of an underweight tablet.	West-Ward Pharmaceutical 1809 Wilson Rd Columbus, OH 43228-9579
Drugs	La' Trim Plus Dietary Supplement Capsules, 350 mg, 60 count bottles, Manufactured for Timeless Solutions, 1810 E Sahara Ave #100, Las Vegas, Nevada 89104, distributed by BeeXtreme LLC, Punxsutawney PA	Class I	All Lots	Marketed without an Approved NDA/ANDA; FDA analysis found them to contain sibutramine and phenolphthalein	Bee Xtreme
Drugs	Oasis Dietary Supplement Capsules, 500 mg, 45 count bottles, Manufactured for Timeless Solutions, 1810 E Sahara Ave #100, Las Vegas, Nevada 89104, distributed by BeeXtreme LLC, Punxsutawney PA	Class I	All Lots	Marketed without an Approved NDA/ANDA; FDA analysis found them to contain sibutramine and phenolphthalein	Bee Xtreme
Drugs	Jenesis Dietary Supplement Capsules, 350 mg, 60 count bottles, Manufactured for	Class I	All Lots	Marketed without an Approved NDA/ANDA; FDA analysis found them to	Bee Xtreme

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
	Timeless Solutions, 1810 E Sahara Ave #100, Las Vegas, Nevada 89104, distributed by BeeXtreme LLC, Punxsutawney PA			contain sibutramine and phenolphthalein	
Drugs	5% Dextrose Injection USP, 100mL in a 150 mL PAB container, Rx only, B. Braun Medical Inc. Irvine, CA 92614-5895 USA, NDC 00264-1510-32	Class I	Lot #: J5J706, Exp. 10/31/2016	Non-Sterility: fungal contamination due to leaking containers.	B. Braun Medical Inc
Drugs	fentaNYL Citrate, 10 mcg per 1 mL, in 0.9% Sodium Chloride, Preservative Free, 1 mL Total Volume in a syringe, For IV Use, Rx only, PharMEDium, Product code 2R3174.	Class I	Lot Number: 15149004M, Exp 08/27/15	Subpotent Drug: confirmed subpotency in one lot of this product that was packaged and stored in syringes.	Pharmedium Services, LLC
Drugs	Diocto Liquid (docusate sodium) 50 mg/5 mL Stool Softener Laxative, One Pint (473 mL) bottles, Dist by: Rugby Laboratories, Livonia, MI --- NDC 0536-0590-85	Class I	20351407, 20351408, exp 09/16; 20351409, exp 11/16; 20351410, exp 12/16; 20351501, 20351502, exp 01/17; 20351503, exp 03/17; 20351504, exp 04/17; 20351505, exp 05/17; 20351506, 20351507, exp 06/17; 20351508, exp 07/17; 20351509, 20351510, exp 10/17; 20351511, 20351512, 20351513, exp 11/17; 20351601, exp 01/18; 20351602, exp 02/18; 20351603, exp 03/18; 20351604, 20351605, exp 04/18	Microbial contamination of Non-Sterile Products; positive findings of Burkholderia cepacia	The Harvard Drug Group
Drugs	atropine Sulfate Injection, 0.4 mg per mL, 1 mg per 2.5 mL, 2.5 mL Total Volume in a syringe, For IV use, Rx only, PharMEDium, Product code 2R3324.	Class II	Lot Numbers: 15146085M, 15147088M, 15149011M, 15149109M, 15150093M, 151730001M, 151740139M, 151900018M, 151910014M, Exp between 07/15/15-10/12/15	Stability Data Does Not Support Expiry: potential loss of potency in drugs packaged and stored in syringes.	Pharmedium Services, LLC
Drugs	atropine Sulfate Injection, 0.4 mg per mL, 0.8 mg per 2 mL, 2 mL Total Volume in a syringe, For IV Use, Rx only, PharMEDium, Product code 2R3335.	Class II	Lot Numbers: 15146082M, 15147001M, 15147099M, 15149110M, 15150028M, 15152055M, 151730002M, 151730129M, 151880317M, 151880330M, 151890300M, 151930022M, 151940213M, 151940288M, Exp between 07/15/15-10/12/15	Stability Data Does Not Support Expiry: potential loss of potency in drugs packaged and stored in syringes.	Pharmedium Services, LLC
Drugs	Buffered Lidocaine, 1%, In Sodium Bicarbonate 8.4%, 1 mL Total Volume in a syringe, Local anesthetic use, Rx only, PharMEDium, Product code 2K2466.	Class II	Lot Numbers: 15194041E, 15195008E, 15195020E, Exp between 07/15/15-10/12/15	Stability Data Does Not Support Expiry: potential loss of potency in drugs packaged and stored in syringes.	Pharmedium Services, LLC
Drugs	Buffered Lidocaine, 2%, In Sodium Bicarbonate 8.4%, 3 mL Total Volume in a syringe, Local	Class II	Lot Number: 15195070E, Exp between 07/15/15-10/12/15	Stability Data Does Not Support Expiry: potential loss of potency in drugs	Pharmedium Services, LLC



Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
	anesthetic use, Rx only, PharMEDium, Product code 2K2475.			packaged and stored in syringes.	
Drugs	ePHEDrine Sulfate, 5 mg per mL, 25 mg per 5 mL, in 0.9% Sodium Chloride, Preservative Free, 5 mL Total Volume in a syringe, For IV Use, Rx only, PharMEDium, Product code 2R3301.	Class II	Lot Numbers: 15112081M, 15113016M, Exp between 07/15/15-10/12/15	Stability Data Does Not Support Expiry: potential loss of potency in drugs packaged and stored in syringes.	Pharmedium Services, LLC
Drugs	ePHEDrine Sulfate, 10 mg per mL, 50 mg per 5 mL, in 0.9% Sodium Chloride, Preservative Free, 5 mL Total Volume in a syringe, For IV Use, Rx only, PharMEDium, Product code 2R3308.	Class II	Lot Numbers: 15112085M, 15112087M, 15112090M, 15113020M, 15113100M, Exp between 07/15/15-10/12/15	Stability Data Does Not Support Expiry: potential loss of potency in drugs packaged and stored in syringes.	Pharmedium Services, LLC
Drugs	ePHEDrine Sulfate, 10 mg per mL, in 0.9% Sodium Chloride, Preservative Free, 1 mL Total Volume in a syringe, For IV Use, Rx only, PharMEDium, Product code 2R3347.	Class II	Lot Numbers: 15118028M, 15118062M, 15125027M, 15126055M, 15131013M, 15133028M, 15139046M, 15146033M, 15146062M, 151880294M, 151890279M, 151930127M, 151940261M, Exp between 07/15/15-10/12/15	Stability Data Does Not Support Expiry: potential loss of potency in drugs packaged and stored in syringes.	Pharmedium Services, LLC
Drugs	Fentanyl Citrate 16.67 mcg per mL and Bupivacaine HCl 0.1667% in 0.9% Sodium Chloride, Total Dose 25.005 mcg/1.5 mL Fentanyl Citrate, Content Volume 1.5 mL in 3 mL BD Syringe, Intended for Epidural Use, Rx only, PharMEDium, Product code 2T6228.	Class II	Lot Numbers: 151000045M, 15127040M, 15133026M, 15141029M, 151930078M, 15132103M, Exp between 07/15/15-10/12/15	Stability Data Does Not Support Expiry: potential loss of potency in drugs packaged and stored in syringes.	Pharmedium Services, LLC
Drugs	fentaNYL Citrate Injection, 50 mcg per mL, Preservative Free, 1 mL Total Volume in a syringe, For IV Use, Product code 2R3118, NDC 61553-118-40	Class II	Lot Number: 15141053M, Exp between 07/15/15-10/12/15	Stability Data Does Not Support Expiry: potential loss of potency in drugs packaged and stored in syringes.	Pharmedium Services, LLC
Drugs	fentaNYL Citrate Injection, 50 mcg per mL, Preservative Free, 1 mL Total Volume in a syringe, For IV Use, Rx only, PharMEDium, Product code 2R3153.	Class II	Lot Numbers: 15100052M, 15103048M, 15104052M, 15118032M, 15127009M, 15127068M, 15134039M, 15135009M, 15135054M, 15140070M, 15147039M, 15148065M, 151900145M, 151930043M, Exp between 07/15/15-10/12/15	Subpotent Drug and Stability Data Does Not Support Expiry: confirmed subpotency and potential loss of potency in drugs packaged and stored in syringes.	Pharmedium Services, LLC
Drugs	fentaNYL Citrate, 10 mcg per 1 mL, in 0.9% Sodium Chloride, Preservative Free, 1 mL Total Volume in a syringe, For IV Use,	Class II	Lot Numbers: 15118074M, 15120007M, 15124007M, 15127060M, 15132006M, 15132039M, 15138059M,	Stability Data Does Not Support Expiry: potential loss of potency in drugs packaged and stored in	Pharmedium Services, LLC

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
	Rx only, PharMEDium, Product code 2R3174.		15139012M, 15139051M, 15140003M, 15141067M, 15146006M, 15148075M, 151730112M, 151730155M, 151740205M, 151880329M, 151930020M, 151930026M, Exp between 07/15/15-10/12/15	syringes.	
Drugs	fentaNYL Citrate, 25 mcg per mL in 0.9% Sodium chloride, 1 mL Total Volume in a syringe, For IV Use, Rx only, PharMEDium, Product code 2R3236.	Class II	Lot Numbers: 15140057M, 15147053M, 15127066M, Exp between 07/15/15-10/12/15	Stability Data Does Not Support Expiry: potential loss of potency in drugs packaged and stored in syringes.	Pharmedium Services, LLC
Drugs	fentaNYL Citrate Injection, 50 mcg per mL (100 mcg per 2 mL), 2 mL Total Volume in a syringe, For IV Use, Rx only, PharMEDium, Product code 2R3303.	Class II	Lot Numbers: 15119083M, 15119086M, 15133078M, 15134127M, 15135064M, 151380066M, 15138007M, 151380108M, 151380109M, 15138060M, 15138063M, 15138064M, 15138065M, 15140043M, 15140082M, 15140084M, 15142093M, 151450033M, 151460093M, 151460094M, 15147097M, 15149047M, 15149108M, 15149112M, 15149113M, 15152051M, 15152053M, 15160010C, 15161003C, 15161004C, 15161007C, 15161008C, 15163003C, 151650036C, 151660042C, 151660043C, 151670006C, 151670007C, 151670008C, 151680044C, 151720006C, 151720013M, 151720106M, 151730140M, 151730141M, 151730143M, 151740003C, 151740004C, 151740137M, 151750008C, 151760042C, 151790004C, 151790040C, 151880332M, 151890122M, 151890123M, 151900009M, 151900137M, 151900178M, 151900243M, 151930033M, 15100140M, 151020015M, 151020016M, 15103004M, 151030057M, 151030092M, 151170046M, 151170087M, 151170088M, 151170089M, 15120066M, 15120068M, 15124083M, 151260091M, 15127016M, 15127089M, 15127092M, 15127093M, 15128108M, 15128109M, 151310088M, 151310089M, 151310101M, 151310102M, 151310104M, 15132007C, 151320098M, 15133003C, 15133013C, 15135011C, 15138006C, 15139012C, 15141001C, 15142004C,	Stability Data Does Not Support Expiry: potential loss of potency in drugs packaged and stored in syringes.	Pharmedium Services, LLC

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
			15142005C, 15147001C, 15147002C, 15147003C, 15147004C, 15147013C, 15147014C, 15149005C, 15152009C, 15154007C, 15155001C, 15155009C, 15156004C, 15157003C, 15159004C, Exp between 07/15/15-10/12/15		
Drugs	fentaNYL Citrate Injection, 50 mcg per mL, 250 mcg per 5 mL, 5mL Total Volume in a syringe, For IV Use, Rx only, PharMEDium, Product code 2R3306.	Class II	Lot Numbers: 15112083M, 15112129M, Exp between 07/15/15-10/12/15	Stability Data Does Not Support Expiry: potential loss of potency in drugs packaged and stored in syringes.	Pharmedium Services, LLC
Drugs	fentaNYL Citrate, 5 mcg per mL, 15 mcg per 3mL, in 0.9% Sodium chloride, 3 mL Total Volume in a syringe, For IV Use, Rx only, PharMEDium, Product code 2R3318.	Class II	Lot Numbers: 15100054M, 15117048M, 15127063M, 15128034M, 15128044M, 15132059M, 15134032M, 15147063M, 15148055M, 151890302M, 151900130M, 151900222M, Exp between 07/15/15-10/12/15	Stability Data Does Not Support Expiry: potential loss of potency in drugs packaged and stored in syringes.	Pharmedium Services, LLC
Drugs	fentaNYL Citrate, 5 mcg per mL (10 mcg per 2 mL) in 0.9% Sodium chloride, 2 mL Total Volume in a syringe, For IV Use, Rx only, PharMEDium, Product code 2R3339.	Class II	Lot Numbers: 15103037M, 15117042M, 15126027M, 15127049M, 15131003M, 15119043M, 15138050M, 15141033M, 15142056M, 15146040M, 15149039M, 151890299M, 151900220M, 151930019M, Exp between 07/15/15-10/12/15	Stability Data Does Not Support Expiry: potential loss of potency in drugs packaged and stored in syringes.	Pharmedium Services, LLC
Drugs	fentaNYL Citrate, 10 mcg per mL (25 mcg per 2.5 mL), in 0.9% Sodium Chloride, 2.5 mL Total Volume in a syringe, For IV Use, Rx only, PharMEDium, Product code 2R3424.	Class II	Lot Numbers: 15103031M, 15127041M, 15139034M, 15140039M, 15141048M, 15147057M, 15147086M, 15148053M, 151880285M, Exp between 07/15/15-10/12/15	Stability Data Does Not Support Expiry: potential loss of potency in drugs packaged and stored in syringes.	Pharmedium Services, LLC
Drugs	fentaNYL Citrate, 5 mcg per mL, 0.9% Sodium Chloride, Preservative Free, 1 mL Total Volume in a syringe, For IV Use, Rx only, PharMEDium, Product code 2R3479.	Class II	Lot Numbers: 15119048M, 15126024M, 15127055M, 15133037M, 15135039M, 15138039M, 15140022M, 15141026M, 15148023M, 15152075M, 151730221M, 151890289M, 151900214M, Exp between 07/15/15-10/12/15	Stability Data Does Not Support Expiry: potential loss of potency in drugs packaged and stored in syringes.	Pharmedium Services, LLC
Drugs	fentaNYL Citrate, 5 mcg per mL (10 mcg per 2 mL) in 0.9% Sodium chloride, 2 mL Total Volume in a 3 mL BD Syringe, For IV Use Only, Rx only, PharMEDium, Product code 2T6107.	Class II	Lot Number: 151900252M, Exp between 07/15/15-10/12/15	Stability Data Does Not Support Expiry: potential loss of potency in drugs packaged and stored in syringes.	Pharmedium Services, LLC
Drugs	glycopyrrolate, 0.2 mg per mL, 0.6 mg per 3 mL, 3 mL Total Volume in a syringe, For IV Use,	Class II	Lot Numbers: 15100141M, 15118066M, 15118083M, 15121090M, 15124001M,	Stability Data Does Not Support Expiry: potential loss of potency in drugs	Pharmedium Services, LLC

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
	Rx only, PharMEDium, Product code 2R3217.		15126042M, 15127036M, 15128030M, 15132065M, 15133010M, 15134007M, 15135010M, 15138062M, 15139002M, 15139003M, 15139052M, 15139053M, 15140083M, 15142002M, 15142090M, 15146084M, 15148044M, 15150014M, 15153002M, 151720016M, 151740133M, 151880151M, 151890120M, 151890239M, 151900019M, 151910015M, 151930042M, Exp between 07/15/15-10/12/15	packaged and stored in syringes.	
Drugs	glycopyrrolate, 0.2 mg per mL, 0.4 mg per 2 mL, 2 mL Total Volume in a syringe, For IV Use, Rx only, PharMEDium, Product code 2R3329.	Class II	Lot Numbers: 15117086M, 15117087M, 15117088M, 15118090M, 15120069M, 15120070M, 15124086M, 15126074M, 15126075M, 15127031M, 15127095M, 15133009M, 15133079M, 15134011M, 15134022M, 15134065M, 15140004M, 15140046M, 15140086M, 15141022M, 15141023M, 15141042M, 15142094M, 15147098M, 15149114M, 15149115M, 151520082M, 151520100M, 151520101M, 151520102M, 15152054M, 151740174M, 151880153M, 151890124M, 151900020M, 151910018M, Exp between 07/15/15-10/12/15	Stability Data Does Not Support Expiry: potential loss of potency in drugs packaged and stored in syringes.	Pharmedium Services, LLC
Drugs	glycopyrrolate, 0.2 mg per mL, 1 mg per 5 mL, 5 mL Total Volume in a syringe, For IV Use, Rx only, PharMEDium, Product code 2R3340.	Class II	Lot Numbers: 15112008M, 15112040M, 15113024M, Exp between 07/15/15-10/12/15	Stability Data Does Not Support Expiry: potential loss of potency in drugs packaged and stored in syringes.	Pharmedium Services, LLC
Drugs	HEPARIN Sodium Inj. USP, 15,000 USP Heparin Units per 3 mL Injection 3 mL Total Volume in a syringe, Rx only, PharMEDium, Product code 2K1210.	Class II	Lot Numbers: 15135098S, 15146063S, 15154082S, Exp between 07/15/15-10/12/15	Stability Data Does Not Support Expiry: potential loss of potency in drugs packaged and stored in syringes.	Pharmedium Services, LLC
Drugs	HEPARIN Sodium Inj., USP, 5,000 USP Heparin Units per 5 mL Total Volume in a syringe, NOT FOR LOCK FLUSH, 1,000 USP Heparin Units per mL, Rx only, PharMEDium, Product code 2K1925.	Class II	Lot Numbers: 15147130S, 15180094S, Exp between 07/15/15-10/12/15	Stability Data Does Not Support Expiry: potential loss of potency in drugs packaged and stored in syringes.	Pharmedium Services, LLC
Drugs	HEPARIN Sodium Inj. USP, 3,000 USP Heparin Units per 3 mL Total Volume in a syringe,	Class II	Lot Numbers: 15138094S, 15148074S, 15152062S, 15159110S, 15180117S, 15183118S, Exp between 07/15/15-	Subpotent Drug and Stability Data Does Not Support Expiry: confirmed	Pharmedium Services, LLC

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
	NOT FOR LOCK FLUSH, 1,000 Heparin USP Units per mL, Rx only, PharMEDium, Product code 2K1926.		10/12/15	subpotency and potential loss of potency in drugs packaged and stored in syringes.	
Drugs	HYDROmorphone HCl, 0.2 mg per mL, (0.4 mg per 2 mL), in 0.9% Sodium Chloride, 2 mL Total Volume in a syringe, For IV Use, Rx only, PharMEDium, Product code 2R3162.	Class II	Lot Numbers: 151200003M, 151260128M, 151300005M, 151310094M, 151320134M, 151320143M, 151340107M, 151370002M, 151390005M, 151390142M, 151400005M, 151400095M, 151400136M, 151470008M, 151510002M, 151520080M, 151880214M, 151890257M, Exp between 07/15/15-10/12/15	Stability Data Does Not Support Expiry: potential loss of potency in drugs packaged and stored in syringes.	Pharmedium Services, LLC
Drugs	HYDROmorphone HCl, 0.5 mg per mL in 0.9% Sodium Chloride, 1 mL Total Volume in a syringe, For IV Use, Rx only, PharMEDium, Product code 2R3352.	Class II	Lot Numbers: 15121069M, 15124075M, 15126078M, 15138012M, 15138013M, 15148077M, 15149122M, 15150103M, 151740201M, 151880159M, 151890210M, Exp between 07/15/15-10/12/15	Stability Data Does Not Support Expiry: potential loss of potency in drugs packaged and stored in syringes.	Pharmedium Services, LLC
Drugs	HYDROmorphone HCl, 1 mg per mL, in 0.9% Sodium Chloride, 1 mL Total Volume in a syringe, For IV Use, Rx only, PharMEDium, Product code 2T6165	Class II	Lot Numbers: 15133058M, 15140061M, 15147056M, 151880295M, Exp between 07/15/15-10/12/15	Stability Data Does Not Support Expiry: potential loss of potency in drugs packaged and stored in syringes.	Pharmedium Services, LLC
Drugs	ketamine HCl, 10 mg per mL, 50 mg per 5 mL, in 0.9% Sodium Chloride, 5 mL Total Volume in a syringe, For IV Use, Rx only, PharMEDium, Product code 2R3234.	Class II	Lot Number: 15112064M, Exp between 07/15/15-10/12/15	Stability Data Does Not Support Expiry: potential loss of potency in drugs packaged and stored in syringes.	Pharmedium Services, LLC
Drugs	ketamine HCl, 10 mg per mL, 50 mg per 5 mL, 0.9% Sodium Chloride, 5 mL Total Volume in a syringe, For IV Use, Rx only, PharMEDium, Product code 2R3320.	Class II	Lot Numbers: 151120100M, 15112020M, 15112094M, 15113012M, Exp between 07/15/15-10/12/15	Stability Data Does Not Support Expiry: potential loss of potency in drugs packaged and stored in syringes.	Pharmedium Services, LLC
Drugs	ketamine HCl, 10 mg per mL, 20 mg per 2 mL, in 0.9% Sodium Chloride, 2 mL Total Volume in a syringe, For IV Use, Rx only, PharMEDium, Product code 2R3330.	Class II	Lot Numbers: 15118003M, 15119077M, 15121002M, 15125019M, 15126067M, 15132022M, 15132038M, 15134043M, 15139009M, 15140006M, 15141004M, 15141065M, 15148045M, 15148070M, 151730156M, 151890125M, 151890208M, 151900010M, 151900125M, 151930044M, 151940270M, Exp between 07/15/15-10/12/15	Stability Data Does Not Support Expiry: potential loss of potency in drugs packaged and stored in syringes.	Pharmedium Services, LLC
Drugs	ketamine HCl Injection, 50 mg	Class	Lot Numbers: 15117083M,	Stability Data Does Not	Pharmedium

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
	per mL, 1 mL Total Volume in a syringe, For IV Use, Rx only, PharMEDium, Product code 2R3348.	II	15117090M, 15118047M, 15121052M, 15124079M, 15126020M, 15127007M, 15127096M, 15133014M, 15133068M, 15134067M, 15139089M, 15140069M, 15141027M, 15141043M, 15142095M, 15146008M, 15149111M, 15149116M, 151730004M, 151730116M, 151880152M, 151890126M, 151930170M, 151940024M, 151940182M, Exp between 07/15/15-10/12/15	Support Expiry: potential loss of potency in drugs packaged and stored in syringes.	Services, LLC
Drugs	ketamine HCl Injection, 50 mg per mL (100 mg per 2 mL), 2 mL Total Volume in a syringe, Rx only, PharMEDium, For IV Use, Product code 2R3500.	Class II	Lot Numbers: 15117045M, 15120050M, 15131014M, Exp between 07/15/15-10/12/15	Stability Data Does Not Support Expiry: potential loss of potency in drugs packaged and stored in syringes.	Pharmedium Services, LLC
Drugs	labetalol HCl, 5 mg per mL, 20 mg per 4 mL, 4 mL total Volume in a syringe, For IV Use, Rx only, PharMEDium, Product code 2R3117.	Class II	Lot Numbers: 15112079M, 15112124M, Exp between 07/15/15-10/12/15	Stability Data Does Not Support Expiry: potential loss of potency in drugs packaged and stored in syringes.	Pharmedium Services, LLC
Drugs	lidocaine HCl, 0.5%, 5 mg per mL, in 0.9% Sodium Chloride, 1 mL Total Volume in a syringe, Rx only, PharMEDium, Product code 2R3140.	Class II	Lot Numbers: 15118068M, 15124072M, 15125066M, 15128033M, 15131001M, 15131017M, 15139035M, 15139080M, 15146036M, 15147054M, 15152078M, 151730126M, 151740218M, 151900292M, Exp between 07/15/15-10/12/15	Stability Data Does Not Support Expiry: potential loss of potency in drugs packaged and stored in syringes.	Pharmedium Services, LLC
Drugs	lidocaine HCl, 1%, 10 mg per 1 mL, 1 mL Total Volume in a syringe, Rx only, PharMEDium, Product code 2R3102.	Class II	Lot Numbers: 15118064M, 15119066M, 15119075M, 15124006M, 15133061M, 15133066M, 15134057M, 15140063M, 15149053M, 151720021M, 151880315M, Exp between 07/15/15-10/12/15	Stability Data Does Not Support Expiry: potential loss of potency in drugs packaged and stored in syringes.	Pharmedium Services, LLC
Drugs	lidocaine HCl, 1%, 30 mg per 3 mL, 3 mL Total Volume in a syringe, Rx only, PharMEDium, Product code 2R3104.	Class II	Lot Numbers: 15117146M, 15121045M, 15125052M, 15131008M, 15133051M, 15140028M, 15149043M, 151890293M, Exp between 07/15/15-10/12/15	Stability Data Does Not Support Expiry: potential loss of potency in drugs packaged and stored in syringes.	Pharmedium Services, LLC
Drugs	lidocaine HCl, 1%, 10 mg per mL (50 mg per 5 mL), 5 mL Total Volume in a syringe, Rx only, PharMEDium, Product code 2R3106.	Class II	Lot Number: 15113014M, Exp between 07/15/15-10/12/15	Stability Data Does Not Support Expiry: potential loss of potency in drugs packaged and stored in syringes.	Pharmedium Services, LLC
Drugs	lidocaine HCl, 1%, in 0.9% Sodium Chloride, Preservative	Class II	Lot numbers: 15118046M, 15128003M, 15128111M,	Stability Data Does Not Support Expiry: potential	Pharmedium Services, LLC

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
	Free, Total Volume 1 mL in a syringe, Rx only, PharMEDium, Product code 2R3345.		15133006M, 15139004M, 15140015C, 15146086M, 15150029M, 15153004M, 151660012C, 151720052C, 151730131C, 151740007C, 151750019C, 151760011C, 151800048C, 151880154M, Exp between 07/15/15-10/12/15	loss of potency in drugs packaged and stored in syringes.	
Drugs	lidocaine HCl 1%, 10 mg per mL (50 mg per 5 mL), Preservative Free, 5 mL Total Volume in a syringe, Rx only, PharMEDium, Product code 2R3391.	Class II	Lot Number: 15113065M, Exp between 07/15/15-10/12/15	Stability Data Does Not Support Expiry: potential loss of potency in drugs packaged and stored in syringes.	Pharmedium Services, LLC
Drugs	lidocaine HCl, 2%, 40 mg per 2 mL, 2 mL Total Volume in a syringe, Rx only, PharMEDium, Product code 2R3112.	Class II	Lot Numbers: 15118067M, 15120045M, 15127005M, 15131002M, 15135005M, 15135046M, 15140001M, 15140045M, 15146007M, 15147070M, 15152052M, 151880331M, 151900241M, Exp between 07/15/15-10/12/15	Stability Data Does Not Support Expiry: potential loss of potency in drugs packaged and stored in syringes.	Pharmedium Services, LLC
Drugs	lidocaine HCl, 2%, Preservative Free, Total Volume 2mL, Product code 2R3323, NDC 61553-323-79	Class II	Lot Numbers: 15119047M, 15124043M, 151340072M, 15134037M, 15148042M, Exp between 07/15/15-10/12/15	Stability Data Does Not Support Expiry: potential loss of potency in drugs packaged and stored in syringes.	Pharmedium Services, LLC
Drugs	lidocaine HCl 2%, Preservative Free, 20 mg per mL (100 mg per 5 mL), 5 mL Total Volume in a syringe, Rx only, PharMEDium, Product code 2R3384.	Class II	Lot Numbers: 15112074M, 15113030M, Exp between 07/15/15-10/12/15	Stability Data Does Not Support Expiry: potential loss of potency in drugs packaged and stored in syringes.	Pharmedium Services, LLC
Drugs	lidocaine HCl, 2%, 20 mg per mL (60 mg per 3 mL), 3 mL Total Volume, Product code 2R3441, NDC 61553-441-80	Class II	Lot Numbers: 15121068M, 15128035M, 15134056M, 15148067M, 15152003M, 151890376M, Exp between 07/15/15-10/12/15	Stability Data Does Not Support Expiry: potential loss of potency in drugs packaged and stored in syringes.	Pharmedium Services, LLC
Drugs	lidocaine HCl, 2%, 20 mg per mL (60 mg per 3 mL), 3 mL Total Volume in a syringe, Rx only, PharMEDium, Product code 2R3450.	Class II	Lot Numbers: 15117053M, 15117054M, 15124056M, 15128001M, 15128002M, 15131021M, 15133067M, 15141028M, 15147089M, 15147090M, 151740185M, 151740188M, Exp between 07/15/15-10/12/15	Stability Data Does Not Support Expiry: potential loss of potency in drugs packaged and stored in syringes.	Pharmedium Services, LLC
Drugs	methadone HCl, 1 mg per mL, in 0.9% Sodium Chloride, 1 mL Total Volume in a syringe, For IV Use Only, Rx only, PharMEDium, Product code 2T6120.	Class II	Lot Numbers: 15118004M, 15119082M, 15134004C, 15134006M, 15139004C, 15139011M, 15140071M, 15141001M, 15141129M, 15147012C, 15147030M, 15148004C, 15150021M, 15155002C, 15160002C, 15160006C, 151730013C,	Stability Data Does Not Support Expiry: potential loss of potency in drugs packaged and stored in syringes.	Pharmedium Services, LLC



Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
			151760016C, 151810002C, 151890129M, Exp between 07/15/15-10/12/15		
Drugs	methadone HCl, 2.5 mg per 0.5 mL, in 0.9% Sodium Chloride, 0.5 mL Total Volume in a syringe, For IV Use Only, Rx only, PharMEDium, Product code 2T6134.	Class II	Lot Numbers: 15149041M, 151720043M, 15100060M, 15127064M, Exp between 07/15/15-10/12/15	Stability Data Does Not Support Expiry: potential loss of potency in drugs packaged and stored in syringes.	Pharmedium Services, LLC
Drugs	methadone HCl, 10 mg per mL, 1 mL Total Volume in a syringe, For IV Use Only, Rx only, PharMEDium, Product code 2T6149.	Class II	Lot Numbers: 15118069M, 15126004M, 151320095M, 15132023M, 15133005C, 15133011M, 15133032M, 15140003C, 15141005C, 15153010C, 151390098M, 15139065M, 15140074M, 151450122M, 15146010M, 15147052M, 15148046M, 15148058M, 15152062M, 15160001C, 151680006C, 151720023M, 151720080M, 151730133M, 151740008C, 151740211M, 151800043C, 151880168M, Exp between 07/15/15-10/12/15	Stability Data Does Not Support Expiry: potential loss of potency in drugs packaged and stored in syringes.	Pharmedium Services, LLC
Drugs	midazolam HCl, 1 mg per mL, in 0.9% Sodium Chloride, 1 mL Total Volume in a syringe, Rx only, PharMEDium, Product code 2R3196.	Class II	Lot Numbers: 15124046M, 15125056M, 15127070M, 15127073M, 15138054M, 15147055M, 15149049M, 151880314M, 151890307M, Exp between 07/15/15-10/12/15	Stability Data Does Not Support Expiry: potential loss of potency in drugs packaged and stored in syringes.	Pharmedium Services, LLC
Drugs	midazolam HCl, 1 mg per mL (3 mg per 3 mL), in 0.9% Sodium Chloride, 3 mL Total Volume in a syringe, For IV Use, Rx only, PharMEDium, Product Code 2R3351.	Class II	Lot Numbers: 15124077M, 15126077M, 15128005M, 15131033M, 15133007C, 15133080M, 15135013C, 15138066M, 15139013C, 15141044M, 15154009C, 15160005C, 151740043C, 151800047C, 151900147M, Exp between 07/15/15-10/12/15	Stability Data Does Not Support Expiry: potential loss of potency in drugs packaged and stored in syringes.	Pharmedium Services, LLC
Drugs	midazolam HCl, 1 mg per mL (2 mg per 2 mL), in 0.9% Sodium Chloride, 2 mL Total Volume in a syringe, For IV Use, Rx only, PharMEDium, Product code 2R3356.	Class II	Lot Numbers: 151170045M, 151170084M, 151170093M, 15117084M, 151180080M, 15118092M, 15118094M, 15119054M, 15120072M, 15121093M, 151240093M, 151240094M, 151240099M, 15124074M, 151250094M, 15126044M, 15126079M, 15126080M, 15127097M, 15127098M, 15128112M, 151310092M, 151310103M, 151310105M, 15131028M, 151320099M, 15133012M, 15133081M, 15134068M, 15134069M, 151380068M,	Stability Data Does Not Support Expiry: potential loss of potency in drugs packaged and stored in syringes.	Pharmedium Services, LLC



Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
			151380106M, 151380112M, 151390138M, 15139090M, 15140088M, 15140089M, 15141045M, 15141074M, 15141075M, 151450030M, 151450032M, 151460097M, 15146083M, 15146087M, 15149001M, 15149005M, 15149118M, 15149119M, 15150104M, 15152056M, 151720012M, 151730078M, 151730138M, 151740019M, 151740141M, 151740143M, 151890127M, 151890128M, 151890305M, 151900021M, 151900022M, 151900140M, 151930073M, 151930171M, 151930173M, Exp between 07/15/15-10/12/15		
Drugs	morphine Sulfate, 0.5 mg per mL, in 0.9% Sodium Chloride, Preservative Free (Contains Sulfites), 1 mL Total Volume in a syringe, For IV use, Rx only, PharMEDium, Product code 2R3017.	Class II	Lot Numbers: 15121035M, 15125026M, 15126061M, 15132040M, 15133041M, 15139084M, 15147038M, 15148024M, 15152044M, 151740022M, 151900205M, Exp between 07/15/15-10/12/15	Stability Data Does Not Support Expiry: potential loss of potency in drugs packaged and stored in syringes.	Pharmedium Services, LLC
Drugs	morphine Sulfate, 0.5 mg per mL, in 0.9% Sodium Chloride, Preservative Free, 1 mL Total Volume in a syringe, For IV Use, Rx only, PharMEDium, Product code 2R3119.	Class II	Lot Numbers: 15117038M, 151200111M, 15126052M, 15127038M, 15131015M, 15134028M, 15134031M, 15135049M, 151380104M, 15139033M, 15139063M, 151410121M, 15146038M, 15147041M, 15149045M, 15152036M, 151730212M, 151890291M, 151930131M, Exp between 07/15/15-10/12/15	Stability Data Does Not Support Expiry: potential loss of potency in drugs packaged and stored in syringes.	Pharmedium Services, LLC
Drugs	morphine Sulfate, 1 mg per mL (5 mg per 5 mL), in 0.9% Sodium Chloride, Preservative Free (Contains Sulfites), 5 mL Total Volume in a syringe, For IV use, Rx only, PharMEDium, Product code 2R3181.	Class II	Lot Numbers: 15113049M, 15113050M, Exp between 07/15/15-10/12/15	Stability Data Does Not Support Expiry: potential loss of potency in drugs packaged and stored in syringes.	Pharmedium Services, LLC
Drugs	morphine Sulfate, 1 mg per mL (2 mg per 2 mL), in 0.9% Sodium Chloride, Preservative Free (Contains Sulfites), 2 mL Total Volume in a syringe, For IV use, Rx only, PharMEDium, Product code 2R3259.	Class II	Lot Numbers: 15125021M, 15126043M, 15126064M, 15126065M, 15126066M, 15127091M, 15132014M, 15133011C, 15134006C, 15134007C, 15134062M, 15135063M, 15139087M, 15141002C, 15141040M, 15141041M, 15146081M, 15147036M, 15147037M, 15147122M, 15148003C, 15148012M, 15148119M, 15149003M, 15152004C, 15153006C, 15154002C,	Stability Data Does Not Support Expiry: potential loss of potency in drugs packaged and stored in syringes.	Pharmedium Services, LLC

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
			15155007C, 15160009C, 151650003C 151660005C, 151660006C, 151670005C, 151720005C, 151720041C, 151730003M, 151730006C, 151730007C, 151730128M, 151740131M, 151740136M, 151750007C, 151790041C, 151930021M, Exp between 07/15/15-10/12/15		
Drugs	morphine Sulfate, 1 mg per mL (2 mg per 2 mL), in 0.9% Sodium Chloride, Preservative Free, 2 mL Total Volume in a syringe, For IV Use, Rx only, PharMEDium, Product code 2R3353.	Class II	Lot Numbers: 15118049M, 15126025M, 15131016M, 15133030M, 15139058M, 15140053M, 15142047M, 15146041M, 15147034M, 15149046M, 151720071M, 151880293M, 151930114M, Exp between 07/15/15-10/12/15	Stability Data Does Not Support Expiry: potential loss of potency in drugs packaged and stored in syringes.	Pharmedium Services, LLC
Drugs	morphine Sulfate, 2 mg per mL, in 0.9% Sodium Chloride, 1 mL Total Volume in a syringe, For IV Use, Rx only, PharMEDium, Product code 2T6455.	Class II	Lot number: 15125033M, Exp between 07/15/15-10/12/15	Stability Data Does Not Support Expiry: potential loss of potency in drugs packaged and stored in syringes.	Pharmedium Services, LLC
Drugs	neostigmine Methylsulfate, 1 mg per mL, 5 mg per 5 mL, 5 mL Total Volume in a syringe, For IV Use, Rx only, PharMEDium, Product code 2R3326.	Class II	Lot Numbers: 15112030M, 15112033M, 15112034M, 15112099M, 15112101M, 15112103M, 15112105M, 15112108M, 15113001M, 15113002M, 15113003M, 15113007M, 15113032M, 15113033M, 15113075M, 15113076M, 15159002S, 15159003S, 15159004S, 15159006S, 15159007S, 15159009S, 15159011S, 15174213S, 15175035S, 15175036S, 15175037S, 15176015S, 15176016S, 15176017S, 15176018S, 15176020S, 15176021S, 15176022S, 15176024S, 15177011S, 15177012S, 15177013S, 15177016S, 15177017S, 15177018S, 15177019S, 15180245S, Exp between 07/15/15-10/12/15	Stability Data Does Not Support Expiry: potential loss of potency in drugs packaged and stored in syringes.	Pharmedium Services, LLC
Drugs	neostigmine Methylsulfate, 1 mg per mL, 2 mg per 2 mL, 2 mL Total Volume in a syringe, For IV Use, Rx only, PharMEDium, Product code 2R3550.	Class II	Lot Numbers: 151880279M, 151890275M, 151930119M, Exp between 07/15/15-10/12/15	Stability Data Does Not Support Expiry: potential loss of potency in drugs packaged and stored in syringes.	Pharmedium Services, LLC
Drugs	neostigmine Methylsulfate, 1 mg per mL, 3 mg per 3 mL, 3 mL Total Volume in a syringe, For IV Use, Rx only, PharMEDium, Product code 2R3551.	Class II	Lot Numbers: 151890186M, 151900229M, 151900255M, 151930138M, 151940246M, Exp between 07/15/15-10/12/15	Stability Data Does Not Support Expiry: potential loss of potency in drugs packaged and stored in syringes.	Pharmedium Services, LLC
Drugs	PHENylephrine HCl, 40 mcg per mL, 200 mcg per 5 mL, in	Class II	Lot Numbers: 15113035M, 15112047M, Exp between 07/15/15-	Stability Data Does Not Support Expiry: potential	Pharmedium Services, LLC

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
	0.9% Sodium Chloride, Preservative Free, 5 mL Total Volume in a syringe, For IV Use, Rx only, PharMEDium, Product code 2R3376.		10/12/15	loss of potency in drugs packaged and stored in syringes.	
Drugs	PHENylephrine HCl, 100 mcg per mL, 0.5 mg per 5 mL, in 0.9% Sodium Chloride, Preservative Free, 5 mL Total Volume in a syringe, For IV Use, Rx only, PharMEDium, Product code 2R3109.	Class II	Lot Number: 15112121M, Exp between 07/15/15-10/12/15	Stability Data Does Not Support Expiry: potential loss of potency in drugs packaged and stored in syringes.	Pharmedium Services, LLC
Drugs	PHENylephrine HCl, 100 mcg per mL, 0.5 mg per 5 mL, in 0.9% Sodium Chloride, Preservative Free, 5 mL Total Volume in a syringe, For IV Use, Rx only, PharMEDium, Product code 2R3346.	Class II	Lot Numbers: 15112107M, 15112110M, 15112113M, 15113025, 15113077M, 15113092M, Exp between 07/15/15-10/12/15	Stability Data Does Not Support Expiry: potential loss of potency in drugs packaged and stored in syringes.	Pharmedium Services, LLC
Drugs	remifentanil HCl, 50 mcg per mL, 100 mcg per 2 mL, in 0.9% Sodium Chloride, Preservative Free, 2 mL Total Volume in a syringe, Rx only, PharMEDium, Product code 2R3300.	Class II	Lot Numbers: 151680012C, 151720013C, 151730179M, 151740029M, 151790014C, 151880319M, 151890297M, 151890318M, 151900127M, 151930081M, Exp between 07/15/15-10/12/15	Stability Data Does Not Support Expiry: potential loss of potency in drugs packaged and stored in syringes.	Pharmedium Services, LLC
Drugs	rocuronium Bromide, 10 mg per mL, 50 mg per 5 mL, Preservative Free, 5 mL Total Volume in a syringe, For IV Use, Rx only, PharMEDium, Product code 2R3321.	Class II	Lot Numbers: 151120168M, 151120169M, 15112027M, 15112096M, 15113021M, 15113080M, 15113081M, 15113082M, 15113083M, 15113084M, 15113085M, 15113086M, 15113087M, 15113088M, Exp between 07/15/15-10/12/15	Stability Data Does Not Support Expiry: potential loss of potency in drugs packaged and stored in syringes.	Pharmedium Services, LLC
Drugs	succinylcholine Chloride Injection, 20 mg per mL, 100 mg per 5 mL, 5 mL Total Volume in a syringe, For IV Use, Rx only, PharMEDium, Product code 2R3357.	Class II	Lot Numbers: 15112035M, 15112036M, 15113006M, 15113026M, 15113078M, Exp between 07/15/15-10/12/15	Stability Data Does Not Support Expiry: potential loss of potency in drugs packaged and stored in syringes.	Pharmedium Services, LLC
Drugs	lidocaine HCl, 1%, in 0.9% Sodium Chloride, Preservative Free, Total Volume 3 mL in a syringe, Rx only, PharMEDium, Product code 2R3343.	Class II	Lot Numbers: 15118063M, 15119033M, 15124035M, 15132062M, 15135014C, 15138006M, 15146004M, 15147009C, 15152042M, 15155003C, 15160004C, 151680013C, 151730130M, 151900142M, 151950033M, Exp between 07/15/15-10/12/15	Stability Data Does Not Support Expiry: potential loss of potency in drugs packaged and stored in syringes.	Pharmedium Services, LLC
Drugs	lidocaine HCl, 2%, 20 mg per mL (100 mg per 5 mL), 5 mL Total Volume in a syringe, Rx	Class II	Lot Number: 15112122M, Exp between 07/15/15-10/12/15	Stability Data Does Not Support Expiry: potential loss of potency in drugs	Pharmedium Services, LLC

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
	only, PharMEDium, Product code 2R3110.			packaged and stored in syringes.	
Drugs	TAZORAC (tazarotene) Gel 0.05%, Rx only, For Dermatologic Use Only, Not for Ophthalmic Use, packaged in a) 30 g tubes (NDC: 0023-8335-03, UPC: 300238335036) and b)100 g tubes,(NDC: 0023-8335-10, UPC: 300238335104), Manufactured by: Allergan Inc., Irvine, CA 92512.	Class II	a) Lot# 82579; Exp. 10/16 b) Lot:# 85088 Exp. 05/17	Failed Content Uniformity Specifications	Allergan Sales, LLC
Drugs	TAZORAC (tazarotene) Gel 0.05%, Rx only, packaged in 15 x 3.5 g professional sample containers, Manufactured by: Allergan Inc., Irvine, CA 92512. UPC: 300238335159.	Class II	Lot # 85037; Exp 05/17 Lot # 82583; Exp 10/16	Failed Content Uniformity Specifications	Allergan Sales, LLC
Drugs	Amikacin Sulfate Injection, USP, 500 mg/2 mL (250 mg/mL) Rx Only, Manufactured in Hungary For: Teva Pharmaceuticals USA, Inc., North Wales, PA 19454, NDC 0703-9032-01 (individual pack), NDC 0703-9032-03 (shelf-pack carton of 10 vials).	Class II	Lot # 7080315, 7400315, 7410315, 7980415	CGMP Deviations	Teva Pharmaceuticals USA
Drugs	Amikacin Sulfate Injection, USP, 1 gm/4 mL (250 mg/mL) Rx Only, Manufactured in Hungary For: Teva Pharmaceuticals USA, Inc., North Wales, PA 19454, NDC 0703-9040-01 (individual pack), NDC 0703-9040-03 (shelf-pack carton of 10 vials).	Class II	Lot # 2381114, 2771114, 4760915	CGMP Deviations	Teva Pharmaceuticals USA
Drugs	Marcaine 0.25% (bupivacaine HCl) injection, USP, 125 mg/50 mL (2.5 mg/mL), 50 mL Multiple-Dose Vial, Rx only, Hospira, Inc., Lake Forest, IL 60045, NDC 0409-1587-50.	Class II	Lot #: 60295DD, Ep 1DEC2017	Lack of Assurance of Sterility and Subpotent Drug: defect in glass vial prevented stopper from forming a seal allowing water to ingress and dilute the product causing it to be less than the labeled potency.	Hospira Inc., A Pfizer Company
Drugs	Marcaine 0.5% (bupivacaine HCl) injection, USP, 250 mg/50 mL (5 mg/mL), 50 mL Multiple-Dose Vial, Rx only, Hospira, Inc., Lake Forest, IL 60045, NDC 0409-1610-50.	Class II	Lot #: 59310DD, Exp 1NOV2017	Lack of Assurance of Sterility and Subpotent Drug: defect in glass vial prevented stopper from forming a seal allowing water to ingress and dilute the product causing it to be less than the labeled potency.	Hospira Inc., A Pfizer Company

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
Drugs	Atropine Sulfate 0.01% in 0.9% Sodium Chloride (Ophthalmic Solution) 10 mL Total Volume in a 15 mL Dropper Bottle, Compounded by Leiter's Compounding, San Jose, CA --- NDC 70360-011-39	Class II	All unexpired lots; Expirations dates of 11/13/2016 to 01/02/2017	Lack of Assurance of Sterility; all compounded products within expiry produced using recalled filters	Leiter's Compounding
Drugs	Brilliant Blue G 0.025% in 0.9% Sodium Chloride (Injection) 1 mL Total Volume in a 2 mL Vial (Preservative Free), Compounded by Leiter's Compounding, San Jose, CA --- NDC 70360-008-35	Class II	All unexpired lots; Expirations dates of .09/20/2016 to 10/10/2016	Lack of Assurance of Sterility; all compounded products within expiry produced using recalled filters	Leiter's Compounding
Drugs	Cefuroxime Sodium 10 mg/mL in 0.9% Sodium Chloride (Injection) 1 mL Total Volume in a 2 mL Vial (Preservative Free), Compounded by Leiter's Compounding, San Jose, CA --- NDC 70360-007-35	Class II	All unexpired lots; Expirations dates of 09/24/2016 to 02/06/2017	Lack of Assurance of Sterility; all compounded products within expiry produced using recalled filters	Leiter's Compounding
Drugs	Cyclopentolate HCl 1% - Tropicamide 1% - PHENYLEphrine HCl 2.5% in Sterile Water for Injection (Ophthalmic Solution), in a) 1 mL Total Volume (NDC 70360-017-38) and b) 10 mL Total Volume (NDC 70360-017-39) in a 15 mL Dropper Bottle, Compounded by Leiter's Compounding, San Jose, CA --- NDC 70360-017-38	Class II	All unexpired lots; a) Expirations dates of 10/03/2016 to 11/06/2016 and b) 09/25/2016 to 10/01/2016	Lack of Assurance of Sterility; all compounded products within expiry produced using recalled filters	Leiter's Compounding
Drugs	Lidocaine HCl 1% - Phenylephrine HCl 1.5% in Sterile Water for Injection (Injection) 1 mL Total Volume in a 2 mL Vial (Preservative Free), Compounded by Leiter's Compounding, San Jose, CA --- NDC 70360-002-35	Class II	All unexpired lots; Expirations dates of 10/03/2016 to 12/19/2016	Lack of Assurance of Sterility; all compounded products within expiry produced using recalled filters	Leiter's Compounding
Drugs	Mitomycin 0.02% (0.2 mg/mL) in Sterile Water for Injection (Injection) 1 mL Total Volume in a 2 mL Vial (Preservative Free), Compounded by Leiter's Compounding, San Jose, CA --- NDC 70360-005-35	Class II	All unexpired lots; Expirations dates of .11/05/2016 to 12/10/2016.	Lack of Assurance of Sterility; all compounded products within expiry produced using recalled filters	Leiter's Compounding
Drugs	Moxifloxacin 1 mg/mL in Sterile Balanced Salt Solution (BSS) Intravitreal Injection, 1 mL Total Volume in a 2 mL Vial, Compounded by Leiter's	Class II	All unexpired lots; Expirations dates of 09/21/2016 to 2/2/2017	Lack of Assurance of Sterility; all compounded products within expiry produced using recalled filters	Leiter's Compounding

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
	Compounding, San Jose, CA --- NDC 70360-003-35				
Drugs	Placebo for Prednisolone Acetate 1%, Oph Suspension, 10 mL Dropper Bottle, Compounded by Leiter's Compounding, San Jose, CA	Class II	All unexpired lots; Expirations dates of 10/11/2016 to 01/16/2017	Lack of Assurance of Sterility; all compounded products within expiry produced using recalled filters	Leiter's Compounding
Drugs	Vancomycin 10 mg/mL in 0.9% Sodium Chloride (Injection) 1 mL Total Volume in a 2 mL Vial (Preservative Free), Compounded by Leiter's Compounding, San Jose, CA --- NDC 70360-005-35	Class II	All unexpired lots; Expirations dates of 10/05/2016 to 01/10/2017	Lack of Assurance of Sterility; all compounded products within expiry produced using recalled filters	Leiter's Compounding
Drugs	ZENATANE (isotretinoin capsules USP) 20 mg, 30 capsules per prescription pack, Rx Only, Manufactured by: Cipla Limited, Kurkumbh Village Pune 4138012 India, Manufactured for: Dr. Reddy's Laboratories Limited Bachupally 500 090 India, NDC 55111-136-81	Class III	Lot # 79KB60205; Exp. 02/18	Failed Dissolution Specifications	Dr. Reddy's Laboratories, Inc.
Drugs	mitoXANTRONE Injection USP (concentrate), 20 mg/10 mL (2 mg/mL), 10 mL Multiple Dose Vial, Rx only, Teva Parenteral Medicines, Inc., Irvine, CA 92618, NDC 0703-4685-01.	Class III	Lot Numbers: 31318574B, Exp 09/16; 31319610B, Exp 07/17; 31320058B, Exp 11/17; 31320497B, Exp 12/17; 31320744B, Exp 02/18	Failed Impurities/Degradation Specifications: potential failure to meet the specification for Impurity D throughout shelf-life.	Teva Pharmaceuticals USA
Drugs	Paricalcitol Capsules, 1 mcg, packaged in 30 Capsules (5 x 6) per carton (NDC 60687-106-25); each blister card containing 6 individually blistered capsules (NDC 60687-106-95), Rx only, Distributed by: American Health Packaging, Columbus, OH, 43217.	Class III	Lot 154341, Exp 03/17	Failed Impurities/Degradation Specifications: This repackaged product was recalled by its manufacturer due to failed results for impurities.	Amerisource Health Services

\*Please refer to FDA website for further information; <http://www.fda.gov/Safety/Recalls/EnforcementReports/default.htm>

# CURRENT DRUG SHORTAGES

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## Tobramycin Injection

September 20, 2016

### Reason of Shortage

- Akorn has recently launched tobramycin solution for injection.
- Fresenius Kabi has tobramycin solution for injection on shortage due to increased demand.
- Mylan Institutional could not provide a reason for the shortage.
- Teva has tobramycin solution for injection on shortage due to manufacturing delays

### Estimated Resupply Dates

- Akorn has tobramycin 40 mg/mL 30 mL vials on back order and the company estimates a release date of early-November 2016.
- Teva has tobramycin 40 mg/mL solution for injection on long term back order and the company estimates a release date of October 2016.
- Mylan Institutional has tobramycin 40 mg/mL 30 mL vials on back order and the company estimates a release date of mid-October 2016.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=701>

## Mupirocin Calcium 2% Cream

September 20, 2016

### Reason of Shortage

- GlaxoSmithKline could not provide a reason for the shortage.
- Prasco discontinued mupirocin calcium 2% cream in February 2016.

### Estimated Resupply Dates

- GlaxoSmithKline has Bactroban 2% cream in 15 gram and 30 gram sizes on back order and the company estimates a release date of 1st quarter 2017.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1206>

## Leflunomide Tablets

September 20, 2016

### Reason of Shortage

- Apotex did not provide a reason for the shortage.
- Heritage states the shortage is due to a delay in obtaining active ingredient.
- Sanofi-Aventis has Arava available.
- Winthrop has leflunomide tablets available.
- Trigen has leflunomide tablets available.

### Estimated Resupply Dates

- Apotex has leflunomide 10 mg and 20 mg tablets on allocation.

- Heritage has leflunomide 10 mg and 20 mg tablets on tight allocation

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=711>

### Haemophilus B Conjugate Vaccine

September 20, 2016

#### Reason of Shortage

- GlaxoSmithKline relaunched Hiberix in August 2016.
- Sanofi Pasteur has ActHIB in short supply due to the shortage of other combination vaccines (eg, Pentacel).
- Merck has PedvaxHIB (Haemophilus b meningococcal protein conjugate vaccine) available.

#### Estimated Resupply Dates

- Sanofi Pasteur has ActHib vaccine on allocation.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1052>

### Ethiodized Oil

September 20, 2016

#### Reason of Shortage

- Guerbet states their Lipiodol product is in short supply due to manufacturing problems at Jubliant HollisterStier, the manufacturing site in Canada that supplies Lipiodol for Guerbet. The company estimates the shortage will last at least one year.

#### Estimated Resupply Dates

- Guerbet is shipping supplies of Lipiodol Ultra-Fluide.2 Lipiodol Ultra-Fluide is not FDA approved. In order to prevent a drug shortage, FDA is allowing Guerbet to import Lipiodol Ultra-Fluide, a product manufactured for Guerbet in France by Delpharm Tours.
- Customers must order Lipiodol Ultra-Fluide directly from Guerbet by calling 1-877-729-6679. Lipiodol Ultra-Fluide is non-refundable and may not be resold.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=618>

### Dexamethasone Sodium Phosphate

September 20, 2016

#### Reason of 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 most dexamethasone sodium phosphate presentations available.
- West-Ward has dexamethasone sodium phosphate available.
- Mylan Institutional 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 all dexamethasone sodium phosphate presentations on intermittent back order and the company is releasing product as it becomes available.
- Fresenius Kabi has dexamethasone 4 mg/mL 1 mL vials on back order and the company estimates a release date of late-September 2016.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=751>

### **BCG Vaccine Live Intravesical**

**September 20, 2016**

#### **Reason of Shortage**

- Sanofi Pasteur states the reason for the shortage is manufacturing delay.
- Merck states the reason for the shortage was increased demand. Merck has Tice BCG readily available.

#### **Estimated Resupply Dates**

- Sanofi Pasteur has TheraCys 81 mg vials for intravesical injection on back order and the company cannot estimate a release date.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=915>

### **Potassium Chloride Injection**

**September 21, 2016**

#### **Reason of Shortage**

- Baxter has a consistent supply of potassium chloride injection.
- Fresenius Kabi has some potassium chloride injection available.
- Hospira has potassium chloride injection on shortage due to increase demand and manufacturing delays.

#### **Estimated Resupply Dates**

- Hospira has potassium chloride 2 mEq/mL 250 mL vials, 30 mEq/15 mL vials, and 10 mEq/500 mL in 5% dextrose and 0.225% sodium chloride on back order and the company cannot estimate a release date.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=696>

### **Hydralazine Injection**

**September 21, 2016**

#### **Reason of Shortage**

- Akorn did not provide a reason for the hydralazine injection on shortage.
- American Regent has hydralazine injection on shortage due to manufacturing delays.

- Fresenius Kabi has hydralazine injection available.
- X-Gen launched hydralazine injection in September 2015.

**Estimated Resupply Dates**

- Akorn has hydralazine 20 mg/mL 1 mL vials in 10 count and 25 count available with expiration dates of July or August 2017.
- American Regent has hydralazine 20 mg/mL 1 mL vials on back order and the company cannot estimate a release date.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1129>

**Erythromycin Lactobionate Injection**

**September 22, 2016**

**Reason of Shortage**

- Pfizer (Hospira) has Erythrocin on shortage due to manufacturing delays.

**Estimated Resupply Dates**

- Pfizer (Hospira) has Erythrocin 500 mg vials on back order and the company estimates a release date of early-November 2016. The 500 mg ADD-Vantage vials are on intermittent back order with regular releases.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=546>

**Methylprednisolone Sodium Succinate Injection**

**September 26, 2016**

**Reason of Shortage**

- Fresenius Kabi states the reason for the shortage was increased demand.
- Pfizer states the reason for the shortage was manufacturing delay.

**Estimated Resupply Dates**

- All presentations are currently available.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1077>

**Calcium Gluconate Injection**

**September 26, 2016**

**Reason of Shortage**

- American Regent has calcium gluconate on shortage due to manufacturing delays.
- Fresenius Kabi has calcium gluconate available.
- American Regent has issued a statement that all lots of calcium gluconate may contain glass particles and filters must be used. Do not use if there are visible glass particles and filter all other product.

### **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 50 mL vials available with expiration dates of <9 months

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=48>

### **Caffeine and Sodium Benzoate Injection**

**September 26, 2016**

#### **Reason of Shortage**

- American Regent could not provide a reason for the shortage of caffeine and sodium benzoate injection.<sup>1</sup>
- American Regent is the sole manufacturer of caffeine and sodium benzoate injection.

#### **Estimated Resupply Dates**

- American Regent has caffeine and sodium benzoate 2 mL vials available.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=817>

### **Ammonium Molybdate Injection**

**September 26, 2016**

#### **Reason of 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 back order and the company cannot estimate a release date.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1003>

### **Zolpidem Tartrate Immediate Release Tablets**

**September 27, 2016**

#### **Reason of Shortage**

- Aurobindo has all presentations listed as inactive.
- Major discontinued zolpidem tartrate immediate release tablets.
- Mylan has most zolpidem presentations available.
- Sandoz has zolpidem available.
- Torrent has zolpidem available.
- Sanofi-Aventis has Ambien available.

#### **Estimated Resupply Dates**

- Mylan has zolpidem 5 mg tablets in 500 count on back order and the company estimates a release date of mid-October 2016.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1219>

### Yellow Fever Vaccine Injection

September 27, 2016

#### Reason of Shortage

- Sanofi Pasteur could not provide a reason for the shortage of YF-Vax.1
- There are no other suppliers of yellow fever vaccine.
- Additional information is available

#### Estimated Resupply Dates

- Sanofi Pasteur has YF-Vax multi-dose vials and single dose vials available in limited supply. Customers can call Sanofi Pasteur to order product for patients traveling in the next 30 days.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=383>

### Thiotepa for Injection

September 27, 2016

#### Reason of Shortage

- West-Ward launched thiotepa in August 2015.
- FDA was allowing temporary importation of Tepadina (thiotepa), from Adienne SA in Italy. There may still be product available at some healthcare centers but importation stopped in December 2015. The solution is similar in formulation to US thiotepa. The main differences between the two products are listed below.
- Tepadina comes in 15 mg and 100 mg vials while the US thiotepa from Bedford only comes in a 15 mg vial. Reconstitution of the products should still yield a final concentration of 10 mg/mL and therefore use caution in choosing vial size and volume of diluent.
- Tepadina is indicated for different uses and therefore different dosing regimens are on the Europe labeling compared to US labeling, but it is the same product as in the US.
- The bar coding for the Italian product will not provide correct information to bar code readers since the manufacturing code is not an NDC number.

#### Estimated Resupply Dates

- West-Ward has thiotepa available with an expiration date of < July 2017.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=589>

### Sodium Phosphate Injection

September 27, 2016

#### Reason of Shortage

- American Regent has sodium phosphate injection on shortage due to manufacturing delay.

- Fresenius Kabi states the reason for the shortage was increased demand.
- Hospira had 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 imported Glycophos available with an expiration date of <6 months.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=770>

### **Piperacillin Tazobactam Injection**

**September 27, 2016**

#### **Reason of Shortage**

- Apotex has piperacillin/tazobactam on shortage due to regulatory delays.
- AuroMedics and Sandoz could not provide a reason for the shortage.
- Baxter has Zosyn frozen premixes on allocation due to increased demand.
- Fresenius Kabi has piperacillin/tazobactam on shortage due to increased demand.
- Mylan Institutional launched piperacillin/tazobactam 3.375 gram and 4.5 gram vials in early-June 2016.
- Pfizer has Zosyn on shortage due to manufacturing delays.
- Sagent has piperacillin/tazobactam on shortage due to increased demand.
- Sandoz discontinued piperacillin/tazobactam in late 2015.
- WG Critical Care states the reason for the shortage is increased demand.

#### **Estimated Resupply Dates**

- Apotex has piperacillin/tazobactam 2.25 gram and 4.5 gram vials on back order and the company cannot estimate a release date. The 3.375 gram and 40.5 gram vials are on back order and the company estimates a release date of mid-October 2016.
- AuroMedics has piperacillin/tazobactam on intermittent back order and the company is releasing product as it becomes available. Check wholesalers for inventory.
- Fresenius Kabi has piperacillin/tazobactam 2.25 gram, 3.375 gram, and 40.5 gram vials on intermittent back order and the company is releasing product as it becomes available. The 4.5 gram vials are on back order and the company estimates a release date of early-November 2016.
- Hospira has piperacillin/tazobactam 2.25 gram vials on intermittent back order and the company is releasing product as it becomes available. The 3.375 gram vials are available in limited supply.
- Pfizer has Zosyn 2.25 gram vials, 3.375 gram vials, 4.5 gram vials, and 40.5 gram vials on back order and the company estimates a release date of January 2018.
- Sagent has piperacillin/tazobactam 3.375 gram and 4.5 gram vials on allocation.
- WG Critical Care has piperacillin/tazobactam 2.25 gram, 3.375 gram, 4.5 gram, and 40.5 gram vials on back order and the company cannot estimate a release date.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1075>

## Lidocaine Injection

September 27, 2016

### Reason of 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 has generic lidocaine presentations on shortage due to a supply interruption of API. Xylocaine products are not affected.
- Hospira has lidocaine presentations on shortage due to manufacturing delays and increased demand.

### Estimated Resupply Dates

- AuroMedics has 1% lidocaine 5 mL ampules on intermittent back order and the company is releasing product as it becomes available. AuroMedics has 2% lidocaine 5 mL vials on intermittent back order and the company is releasing product as it becomes available.
- Fresenius Kabi has 1% lidocaine 2 mL and 10 mL vials on back order and the company estimates a release date of mid-October 2016 for the 2 mL vials and late-September for the 10 mL vials. The 2% lidocaine 2 mL and 5 mL vials are on back order and the company estimates a release date of mid-October 2016 for the 2 mL vials and late-September 2016 for the 5 mL vials. The 1% Xylocaine-MPF 10 mL sterile-pack vials are on back order and the company estimates a release date of early-November 2016. The 1% Xylocaine 20 mL vials are on intermittent back order and the company is releasing product as it becomes available. The 2% Xylocaine 20 mL and 50 mL vials are on intermittent back order and the company is releasing product as it becomes available.
- Hospira has 1% lidocaine 30 mL vials, preservative free, in sterile pack on back order and the company cannot estimate a release date. The 0.5% lidocaine 50 mL vials and 1% lidocaine 20 mL and 50 mL vials are available in limited supply. The 2% lidocaine 50 mL vials are on back order and the company estimates a release date of late-September 2016.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=701>

## Indomethacin Capsules

September 27, 2016

### Reason of Shortage

- Heritage and Teva did not provide a reason for the shortage.
- Sandoz discontinued indomethacin in mid-2016.

### Estimated Resupply Dates

- Heritage has indomethacin 50 mg capsules in 100 count and 500 count on back order and the company estimates a release date of mid-October 2016. The 25 mg capsules in 100 count and 1000 count are on allocation.
- Teva has all indomethacin presentations temporarily unavailable and the company cannot estimate a release date.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1236>

## Flumazenil Injection

September 27, 2016

### Reason of Shortage

- Fresenius Kabi had flumazenil on shortage due to short-term manufacturing delays.
- Mylan Institutional cannot provide a reason for the shortage.
- Sandoz discontinued flumazenil injection in 2015.
- West-Ward states the reason for the shortage is increased demand. West-Ward is not actively marketing flumazenil 5 mL (NDC 00641-6032-10) and 10 mL (NDC 00641-6031-10) vials. Alternate NDCs are available.

### Estimated Resupply Dates

- Mylan Institutional has flumazenil 0.1 mg/mL 5 mL vials on back order and the company estimates a release date of late-October 2016.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1184>

## Ferrous Sulfate Oral Pediatric Drops

September 27, 2016

### Reason of Shortage

- Several liquid products were affected by a recall from PharmaTech due to potential contamination from *B. cepacia*. These included the ferrous sulfate liquid products from Akorn and Major. FDA issued a MedWatch report with the products affected.

### Estimated Resupply Dates

- Akorn has RX Choice Ferrous Sulfate 15 mg/mL 50 mL bottles on back order and the company estimates a release date in late-October 2016.
- Major has Fer-Iron and generic ferrous sulfate 15 mg/mL 50 mL bottles on back order and the company estimates a release date in mid-October 2016.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1246>

## Etomidate Injection

September 27, 2016

### Reason of Shortage

- American Regent had etomidate injection on shortage due to manufacturing delays.
- Ben Venue stopped production in its plant in Bedford, Ohio and closed in July 2014.
- Hospira has Amidate on shortage due to manufacturing delays.
- Par Sterile Products discontinued etomidate in early 2015.
- Sagent is no longer marketing etomidate.

### Estimated Resupply Dates

- Hospira has etomidate 20 mL LifeShield syringes, 10 mL ampules, and 20 mL ampules on back order and the company cannot estimate a release date.

- Mylan Institutional has etomidate 20 mL vials on back order and the company estimates a release date of early-December 2016.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=419>

### **Dextrose (50%) Injection**

**September 27, 2016**

#### **Reason of Shortage**

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

#### **Estimated Resupply Dates**

- Hospira has 50% dextrose 50 mL vials available in limited supply with regular releases.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1012>

### **23.4% Sodium Chloride Concentrated Solution for Injection**

**September 27, 2016**

#### **Reason of Shortage**

- Fresenius Kabi had sodium chloride concentrated solution on shortage due to increased demand.
- Hospira has 23.4% sodium chloride solutions for injection on shortage due to increased demand.

#### **Estimated Resupply Dates**

- Hospira has 23.4% sodium chloride 250 mL bulk containers on back order and the company cannot estimate a release date.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1194>

### **Leucovorin Calcium Injection**

**September 29, 2016**

#### **Reason of Shortage**

- Fresenius Kabi has leucovorin on shortage due to increase demand.
- Teva has leucovorin on allocation due to increased demand.
- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired leucovorin calcium injection from Bedford in July 2014. West-Ward is not actively marketing leucovorin calcium injection at this time.
- Sagent has leucovorin on shortage due to manufacturing delay.

#### **Estimated Resupply Dates**

- Fresenius Kabi has leucovorin 200 mg and 500 mg vials on allocation.



- Sagent has leucovorin 50 mg vials on back order and the company estimates a release date of October 2016. Leucovorin 200 mg vials are on allocation. The 350 mg vials are available with an expiration date of November 2016.
- Teva has leucovorin 100 mg vials on allocation.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=488>

### **Tetracaine Hydrochloride Ophthalmic Drops**

**October 4, 2016**

#### **Reason of Shortage**

- Alcon and OCuSOFT did not provide a reason for the shortage

#### **Estimated Resupply Dates**

- Alcon has tetracaine 0.5% ophthalmic drops in 2 mL bottles on back order and the company cannot estimate a release date.
- OCuSOFT has Tetravisc 0.5% 5 mL bottles and 0.6 mL unit-dose in 12 count on back order and the company cannot estimate a release date.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1242>

### **Oxytocin Injection**

**October 4, 2016**

#### **Reason of Shortage**

- Fresenius Kabi states the shortage was due to increased demand.
- Par Sterile Products (formerly JHP) discontinued generic oxytocin injection in July 2014. Par Sterile Products discontinued Pitocin 10 unit/mL 50 mL vials in September 2015.
- West-Ward is not actively marketing oxytocin.

#### **Estimated Resupply Dates**

- Fresenius Kabi has oxytocin 10 units/mL 30 mL vials on back order and the company estimates a release date of late-October 2016

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=876>

### **Ketorolac Tromethamine Injection**

**October 4, 2016**

#### **Reason of Shortage**

- BD Rx has ketorolac injection available. BD RX is now part of Fresenius Kabi.
- Fresenius Kabi has ketorolac injection available.
- Hospira has ketorolac injection available.
- 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.

- 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**

- Sagent has ketorolac 30 mg/mL 1 mL vials on back order and the company estimates a release date of October 2016. Ketorolac 30 mg/mL 2 mL vials for intramuscular injection are on allocation.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=593>

**Diltiazem Extended-Release Capsules (Twice-Daily Dosing)**

**October 4, 2016**

**Reason of Shortage**

- Mylan and Mylan Institutional do not provide a reason for the shortage.

**Estimated Resupply Dates**

- Mylan has diltiazem 60 mg and 120 mg extended-release capsules in 100 count bottles on back order and the company estimates a release date in early-October 2016. Diltiazem 90 mg extended-release capsules in 100 count bottles are on back order and the company estimate a release date in late-October 2016.
- Mylan Institutional has diltiazem 60 mg, 90 mg, and 120 mg extended-release capsules in 100 count blister packs on back order and the company estimates a release date in mid-November 2016 for the 90 mg and 120 mg capsules and late-November 2016 for the 60 mg capsules.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1250>

**Carboplatin Solution for Injection**

**October 4, 2016**

**Reason of Shortage**

- Bedford discontinued carboplatin in May, 2011 to concentrate on the manufacturing of other products.
- Fresenius Kabi has carboplatin on shortage due to increased demand for the product.
- Hospira has carboplatin injection available.
- Mylan Institutional cannot provide a reason for the shortage.
- Sagent states the reason for the shortage is increased demand for the product.
- Sandoz has discontinued carboplatin injection.
- Teva states the reason for the shortage is increased demand for the product.

**Estimated Resupply Dates**

- Fresenius Kabi has carboplatin 45 mL vials on back order and the company cannot estimate a release date.
- Mylan Institutional has all carboplatin injection on back order and the company cannot estimate a release date.

- Sagent has carboplatin 5 mL, 15 mL, and 60 mL vials on back order and the company cannot estimate a release date. Carboplatin 45 mL vials are on allocation.
- Teva has carboplatin 45 mL and 60 mL vials on allocation.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1005>

### **Ampicillin Sulbactam**

**October 4, 2016**

#### **Reason of Shortage**

- Mylan Institutional discontinued ampicillin sulbactam 1.5 gram and 3 gram vials.
- Pfizer (Hospira) has discontinued their generic ampicillin sulbactam products.
- Sandoz cannot provide a reason for the shortage.
- Sagent has ampicillin sulbactam vials on allocation due to increased demand for the product.
- WG Critical Care states the shortage is due to increased demand.

#### **Estimated Resupply Dates**

- AuroMedics has ampicillin sulbactam 3 gram and 15 gram vials on intermittent back order and the company is releasing product as it becomes available.
- Fresenius Kabi has ampicillin sulbactam 1.5 gram, 3 gram, and 15 gram vials on back order and the company cannot estimate a release date.
- Sagent has ampicillin sulbactam 1.5 gram and 15 gram vials on back order and the company estimates a release date of October 2016. The 3 gram vials are on allocation.
- 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 a weekly allocation. The 15 gram vials are on back order and the company cannot estimate a release date.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=805>

### **Octreotide Injection**

**October 5, 2016**

#### **Reason of Shortage**

- Fresenius Kabi did not provide a reason for the shortage.
- Sagent has octreotide on shortage due to manufacturing delays.
- Teva is relaunching several presentations this year.
- Sun Pharm did not provide a reason for the shortage.

#### **Estimated Resupply Dates**

- Fresenius Kabi has octreotide 50 mcg/mL 1 mL vials on back order and the company estimates a release date of 1st quarter 2017.
- Sagent has octreotide 50 mcg/mL 1 mL vials and 200 mcg/mL 5 mL vials on allocation.
- Sun Pharma cannot provide availability information at this time.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=803>

## Multiple Vitamins for Infusion

October 5, 2016

### Reason of Shortage

- Hospira states the shortage is due to manufacturing delays.
- Baxter has all presentations fully available at this time.

### Estimated Resupply Dates

- Hospira has MVI Adult 10 mL two-chambered vials, MVI-12 without vitamin K 50 mL Dual vials, and MVI Adult 50 mL Dual vials on back order and the company cannot estimate a release date. The MVI Adult 5 mL Dual vials are on back order and the company estimates a release date of late-4th quarter 2016.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1242>

## Methylene Blue Injection

October 5, 2016

### Reason of Shortage

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

### Estimated Resupply Dates

- Akorn has methylene blue on allocation.
- American Regent has ProvayBlue 5 mg/mL 10 mL ampules available.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=27>

## Dihydroergotamine Mesylate Injection

October 5, 2016

### Reason of Shortage

- Perrigo and Valeant did not provide a reason for the shortage.

### Estimated Resupply Dates

- Perrigo has dihydroergotamine 1 mg/mL 1 mL ampules in 5 count and 10 count on back order and the company estimates a release date of January 2017 for the 5 count and mid-November 2016 for the 10 count presentations.
- Valeant has D.H.E. 45 1 mg/mL 1 mL ampules on back order and the company cannot estimate a release date.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1050>

## Thrombin Topical Solution (Bovine)

October 8, 2016

### Reason of Shortage

- Pfizer states the reason for the shortage is manufacturing delay.
- Recombinant thrombin topical solution products (Recothrom) are available and not affected by this shortage.

### Estimated Resupply Dates

- Pfizer has Thrombin JMI 5,000 unit syringe spray kits on back order and the company estimates a release date of mid-October 2016. Thrombin JMI 5,000 unit epistaxis kits are on back order and the company estimates a release date of November 2016

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1199>

## Sodium Acetate Injection

October 8, 2016

### Reason of Shortage

- American Regent has sodium acetate injection on back order due to manufacturing delays.
- Fresenius Kabi has sodium acetate injection available.
- Hospira had sodium acetate injection on back order due to increased demand.

### Estimated Resupply Dates

- American Regent has sodium acetate 2 mEq/mL 20 mL vials and 4 mEq/mL 50 mL vials on long-term back order and the company cannot estimate a release date.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=762>

## Potassium Acetate Injection

October 8, 2016

### Reason of Shortage

- American Regent has potassium acetate on shortage due to manufacturing delays.
- Hospira had potassium acetate on shortage due to increased demand.
- Exela received FDA approval for potassium acetate injection in late-December 2015. Exela has potassium acetate injection available.

### Estimated Resupply Dates

- American Regent has potassium acetate 2 mEq/mL 20 mL vials and 4 mEq/mL 50 mL vials on back order and the company cannot estimate a release date.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=668>

## Penicillin G Benzathine/Penicillin G Procaine

October 8, 2016

### Reason of Shortage

- Pfizer has Bicillin C-R and Bicillin C-R 900/300 on shortage due to manufacturing delays.

### Estimated Resupply Dates

- Pfizer has Bicillin C-R 1,200,000 units/2 mL prefilled syringes on back order and 1,200,000 units/2 mL pediatric prefilled syringes on back order and the company estimates a release date of late-December 2016.
- Pfizer has Bicillin C-R 900/300 2 mL pediatric prefilled syringes on allocation.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1249>

## Penicillin G Benzathine

October 8, 2016

### Reason of Shortage

- Pfizer states the shortage is due to a delay in the manufacturing process.

### Estimated Resupply Dates

- Pfizer has Bicillin L-A 600,000 unit/ 1 mL syringes, 1,200,000 unit/ 2 mL syringes, and 2,400,000 unit/ 4 mL syringes on allocation.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1232>

## Morphine Injections

October 8, 2016

### Reason of Shortage

- Astramorph injection has been unavailable since 2012. Fresenius Kabi changed manufacturing sites and cannot estimate if Astramorph will return.
- Hospira states the shortage is due to manufacturing delays.
- West-Ward launched several new morphine sulfate products in late-September 2015. They are not actively marketing the 15 mg/mL 1mL vials.

### Estimated Resupply Dates

- Hospira has morphine 2 mg/mL 1 mL iSecure syringes on intermittent back order and the company is releasing product as it becomes available. Morphine 25 mg/mL 4 mL and 10 mL ADD-Vantage vials are on back order and the company cannot estimate a release date.
- BD Rx has morphine 8 mg/mL 1 mL syringes on back order and the company estimates a release date of late-October 2016.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=664>

## Magnesium Sulfate Injection

October 8, 2016

### Reason of Shortage

- American Regent has had magnesium sulfate unavailable since late 2012.
- Fresenius Kabi has magnesium sulfate injection on shortage due to increased demand for the product. The company has launched 2 new NDC codes for magnesium sulfate 20 mL and 50 mL vials (these replace the older codes of the 20 mL (NDC 63323-0064-20) and 50 mL (NDC 63323-0064-50) vials).
- Hospira has magnesium sulfate injection on shortage due to manufacturing delays.
- X-Gen has magnesium sulfate injection on shortage due to increased demand.

### Estimated Resupply Dates

- Fresenius Kabi has magnesium sulfate 500 mg/mL 10 mL, 20 mL, and 50 mL vials on intermittent back order and the company is releasing product as it becomes available.
- Hospira has magnesium sulfate 500 mg/mL 20 mL vials on back order and the company estimates a release date of 1st quarter 2018.
- X-Gen has magnesium sulfate 500 mg/mL 10 mL vials on intermittent back order and the company is releasing product as it becomes available.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=757>

## Cisplatin Injection

October 8, 2016

### Reason of Shortage

- Fresenius Kabi did not provide a reason for the shortage.
- Mylan Institutional could not provide a reason for the shortage.
- Teva was allocating cisplatin to prevent stockpiling.
- WG Critical Care could not provide a reason for the shortage.

### Estimated Resupply Dates

- Mylan Institutional has cisplatin 50 mL and 100 mL vials on back order and the company cannot estimate a release date.
- Fresenius Kabi has cisplatin 200 mL vials available with short expiration dating (< 8 months).

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=57>

## Cefotaxime Injection

October 8, 2016

### Reason of 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 increased demand

### **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.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=826>

### **Atropine Sulfate Injection**

**October 8, 2016**

#### **Reason of Shortage**

- Hospira states the shortage was due to manufacturing delays.

### **Estimated Resupply Dates**

- Hospira has atropine 0.1 mg/mL 10 mL Ansyng syringes and 0.05 mg/mL 5 mL Ansyng syringes on back order and the company estimates a release date of late-October 2016.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=814>

### **Vitamin E Aqueous Oral Solution**

**October 11, 2016**

#### **Reason of Shortage**

- Hospira is changing manufacturing sites from a 3rd party manufacturer to in-house manufacturing. This has caused a delay in production.
- Geritrex could not provide a reason for the vitamin E drops shortage.
- Silarx could not provide a reason for the vitamin E drops shortage.

### **Estimated Resupply Dates**

- Hospira has both Aquasol E Drop products on back order and the company cannot estimate a release date.
- Geritrex has vitamin E drops on back order and the company cannot estimate a release date.
- Silarx has vitamin E drops on back order and the company estimates a release date in mid-October 2016.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=965>

### **Vitamin C**

**October 11, 2016**

#### **Reason of Shortage**

- Rugby has vitamin C oral syrup on back order due to a product recall from PharmaTech. More information is available on the FDA website.

### **Estimated Resupply Dates**

- Rugby has vitamin C oral syrup on back order, and the company estimates a resupply date of late-October 2016.



<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1251>

### **Poliovirus Vaccine Inactivated**

**October 11, 2016**

#### **Reason of Shortage**

- Sanofi Pasteur has IPOL vaccine on allocation due to the shortage of other combination vaccines (e.g., Pentacel).

#### **Estimated Resupply Dates**

- Sanofi Pasteur has IPOL vaccine on allocation.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1228>

### **Methylphenidate Transdermal**

**October 11, 2016**

#### **Reason of Shortage**

- Noven has Daytrana patches on shortage due to shipping delays.

#### **Estimated Resupply Dates**

- Noven has all Daytrana presentations on intermittent back order and the company is releasing supplies as they become available.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1216>

### **Gadoteridol Injection**

**October 11, 2016**

#### **Reason of Shortage**

- Bracco diagnostics could not provide a reason for the shortage.

#### **Estimated Resupply Dates**

- Bracco diagnostics has ProHance 15 mL and 20 mL vials on allocation. ProHance 10 mL vials are on back order and the company estimates a release date in mid-October 2016.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1237>

### **Tigecycline Injection**

**October 11, 2016**

#### **Reason of Shortage**

- Pfizer has Tygacil on shortage due to manufacturing delays. The company is supplying 50 mg/5 mL vials during the shortage of the 10 mL vials.

### **Estimated Resupply Dates**

- Pfizer has Tygacil 50 mg/10 mL vials on back order and the company estimates a release date of 2nd quarter 2017.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1218>

### **Promethazine Injection**

**October 12, 2016**

#### **Reason of Shortage**

- Teva states the shortage is due to manufacturing delays.
- West-Ward states the shortage was due to manufacturing delays.
- Hospira discontinued promethazine in 2016.
- X-Gen has promethazine available.

### **Estimated Resupply Dates**

- Teva has all promethazine injection presentations on back order and the company estimates a release date of January 2017.
- West-Ward has promethazine 25 mg/mL 1 mL ampules on a weekly allocation. Phenergan 25 mg/mL 1 mL ampules are on back order and the company estimates a release date of October 2016.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=654>

### **Nalbuphine Injection**

**October 12, 2016**

#### **Reason of Shortage**

- Hospira has nalbuphine injection on shortage due to manufacturing delays.

### **Estimated Resupply Dates**

- Hospira has nalbuphine 10 mg/mL 1 mL ampules available in limited supply. The 10 mg/mL 10 mL vials are on back order and the company estimates a release date of mid-November 2016.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=665>

### **Flurandrenolide Tape**

**October 12, 2016**

#### **Reason of Shortage**

- Allergan states the shortage is due to manufacturing delays.
- Allergan is the sole supplier of flurandrenolide tape.

### **Estimated Resupply Dates**

- Allergan has Cordran tape on back order and the company estimates a release date of late-October 2016.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1241>

### Epinephrine Injection

October 12, 2016

#### Reason of Shortage

- American Regent discontinued both epinephrine presentations in early 2015.
- Amphastar has epinephrine available.
- BPI Labs has epinephrine available.
- Hospira has epinephrine syringes on shortage due to manufacturing delays.
- Par has Adrenalin available.

#### Estimated Resupply Dates

- Hospira has epinephrine 0.1 mg/mL 10 mL 18 gauge Abboject syringes on back order and the company cannot estimate a release date.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=685>

### Ceftazidime Injection

October 12, 2016

#### Reason of Shortage

- IGI Laboratories changed its name to Teligent in late-October 2015.
- Covis divested Fortaz injection to IGI Laboratories in October 2015.
- Hospira had Tazicef on shortage due to manufacturing delays.
- Sagent has ceftazidime injection on shortage due to manufacturing delays.
- Sandoz discontinued ceftazidime 1 gram and 2 gram vials in 2015.

#### Estimated Resupply Dates

- Teligent has Fortaz 6 gram vials on back order and the company estimates a release date of 1st quarter 2017. The 1 gram/50 mL premixed bags are on back order and the company cannot estimate a release date.
- Sagent has ceftazidime 1 gram, 2 gram, and 6 gram vials on back order and the company estimates a release date of November 2016.
- Hospira has Tazicef 1 gram and 2 gram ADD-Vantage vials on back order and the company estimates a release date of late-October 2016. Tazicef 6 gram vials are on back order and the company estimates a release date of mid-January 2017.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=869>

### Ioversol Injection

October 13, 2016

#### Reason of Shortage

- Guerbet could not provide a reason for the Optiray shortage.

### **Estimated Resupply Dates**

- Guerbet has most Optiray products on allocation or back order and the company is releasing supplies as they become available.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1253>

### **Vancomycin Hydrochloride Injection**

**October 14, 2016**

#### **Reason of Shortage**

- Hospira had vancomycin on shortage due to increased demand.
- Fresenius Kabi has vancomycin injection on shortage due to increased demand.
- Mylan Institutional has vancomycin injection available.
- Baxter is allocating vancomycin.
- Sagent had vancomycin injection on allocation due to increased demand.

#### **Estimated Resupply Dates**

- Fresenius Kabi has vancomycin 5 gram and 10 gram vials on intermittent back order and the company is releasing product as it becomes available.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=132>

### **Scopolamine Transdermal Patch**

**October 14, 2016**

#### **Reason of Shortage**

- Baxter has Transderm Scop on shortage due to a manufacturing hold.
- Sandoz has Transderm Scop on shortage due to increased demand.

#### **Estimated Resupply Dates**

- Baxter has Transderm Scop in 10 count on allocation. The 24 count presentation is on back order and the company estimates a release date of October 2016.
- Sandoz has Transderm Scop in 4 count on back order and the company estimates a release date of late-October 2016.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=837>

### **Procainamide Hydrochloride Injection**

**October 14, 2016**

#### **Reason of Shortage**

- Hospira (Pfizer) has procainamide hydrochloride injection on shortage due to manufacturing delays.

#### **Estimated Resupply Dates**

- Hospira has procainamide 500 mg/mL 2 mL vials on back order and the company estimates a release date of 4th quarter 2018. The 100 mg/mL 10 mL vials are available in limited supply.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=868>

### Indocyanine Green

**October 14, 2016**

#### Reason of Shortage

- Akorn could not provide a reason for the shortage.
- Hub Pharmaceuticals states the reason for the shortage was increased demand.

#### Estimated Resupply Dates

- All marketed presentations are available.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1107>

### Benztropine Injection

**October 14, 2016**

#### Reason of Shortage

- American Regent discontinued benztropine injection in May 2015.
- Fresenius Kabi launched benztropine in September 2016.

#### Estimated Resupply Dates

- All marketed presentations are available.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1042>

### Orphenadrine Citrate Injection

**October 17, 2016**

#### Reason of Shortage

- Akorn has orphenadrine citrate injection on shortage due to manufacturing delays.
- Actavis and Sagent did not provide a reason for the orphenadrine citrate shortage

#### Estimated Resupply Dates

- Actavis has orphenadrine injection on back order and the company cannot estimate a release date.
- Akorn has orphenadrine injection on back order and the company cannot estimate a release date.
- Sagent has orphenadrine injection on back order and the company cannot estimate a release date.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=884>

## Meningococcal Vaccines

October 17, 2016

### Reason of Shortage

- Sanofi Pasteur cannot provide a reason for the shortage.
- GlaxoSmithKline acquired Bexsero and Menveo from Novartis Vaccines and Diagnostics in 2015.
- GlaxoSmithKline did not provide a reason for the shortage.
- Pfizer has Trumenba available.

### Estimated Resupply Dates

- Quadrivalent Meningococcal Polysaccharide Vaccine (MPSV4)
- Sanofi Pasteur has Menomune-A/C/Y/W-135 on back order and the company cannot estimate a release date.
- Meningococcal Group B Vaccine
- GlaxoSmithKline has Bexsero prefilled syringes in 1 count and 10 count on back order and the company estimates a release date in late-October 2016.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1192>

## Liotrix Tablets

October 17, 2016

### Reason of Shortage

- Thyrolar tablets from Actavis (formerly Forest) are on shortage due to manufacturing changes.

### Estimated Resupply Dates

- Actavis (formerly Forest) has all Thyrolar presentations on long-term back order and the company cannot estimate a release date.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=24>

## Diphtheria, Tetanus Toxoid, and Acellular Pertussis Vaccine (DTaP)

October 17, 2016

### Reason of Shortage

- Sanofi Pasteur has Daptacel in short supply due to the shortage of other combination vaccines (eg, Pentacel).
- GlaxoSmithKline has Infanrix available.

### Estimated Resupply Dates

- Sanofi Pasteur has Daptacel vaccine on allocation.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=922>

## Diphtheria, Tetanus Toxoid, and Acellular Pertussis and Inactivated Poliovirus and Haemophilus B Conjugate Vaccine (DTaP - IPV/Hib)

October 17, 2016

### Reason of Shortage

- Sanofi Pasteur states the reason for the shortage is manufacturing delay.

### Estimated Resupply Dates

- Sanofi Pasteur has Pentacel vaccine on allocation.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=921>

## Dibucaine Ointment

October 17, 2016

### Reason of Shortage

- Geritrex and Fougera cannot provide a reason for the shortage.
- Geritrex introduced dibucaine 1% ointment in March 2014.
- Novartis divested the rights for all Nupercainal ointment products to Ducere Pharma in 2013.
- These products are available Over-The-Counter.

### Estimated Resupply Dates

- Fougera has dibucaine ointment on long-term back order and the company cannot estimate a release date.
- Geritrex has dibucaine ointment on back order and the company estimates a release date in late-October 2016.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1074>

## Chlorothiazide Oral Suspension

October 17, 2016

### Reason of Shortage

- Valeant could not provide a reason for the shortage.

### Estimated Resupply Dates

- Valeant has chlorothiazide oral suspension (Diuril) on back order, and the company cannot provide an estimated resupply date.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1076>

## Cefepime Injection

October 17, 2016

### Reason of Shortage

- Apotex could not provide a reason for the shortage.

- BBraun has cefepime on allocation due to increased demand.
- Baxter has cefepime on shortage due to increased demand.
- Fresenius Kabi has cefepime injection on shortage due to manufacturing delays.
- Sagent has cefepime injection on shortage due to manufacturing delays.
- WG Critical Care has cefepime injection on shortage due to increased demand.
- Hospira has Maxipime on shortage due to manufacturing delays.
- Sandoz discontinued cefepime injection in early 2016.

#### **Estimated Resupply Dates**

- Apotex has all presentations of cefepime on back order and the company estimates a release date in late-October 2016. Braun has cefepime 1 and 2 gram premixed bags on allocation to contracted customers.
- Baxter has cefepime 1 gram/50 mL and 2 gram/100 mL premixed bags on allocation.
- Fresenius Kabi has cefepime 1 gram and 2 gram vials on back order and the company estimates a release date of 4th quarter 2016.
- Hospira has Maxipime 1 gram ADD-Vantage vials, 2 gram ADD-Vantage vials, and 2 gram vials on allocation. The 1 gram vials are on back order and the company estimates a release date of 1st quarter to 2nd quarter 2017.
- Sagent has cefepime 1 gram and 2 gram vials on back order and the company estimates a release date of November 2016.
- WG Critical Care has cefepime 1 gram and 2 gram vials on back order and the company cannot estimate a release date for the 1 gram vials and estimates a release date of October 2016 for the 2 gram vials.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1176>

### **Acetylcysteine Oral and Inhalation Solution**

**October 17, 2016**

#### **Reason of Shortage**

- American Regent has a consistent supply of acetylcysteine oral and inhalation solution.
- Roxane Labs discontinued acetylcysteine oral and inhalation solution in April 2014.
- Hospira states the reason for the shortage was manufacturing delays.
- Fresenius Kabi states the reason for the shortage was manufacturing delays.

#### **Estimated Resupply Dates**

- American Regent has acetylcysteine solution 100 mg/mL 10 mL vials and 200 mg/mL 10 mL vials on back order and the company cannot estimate a release date. Acetylcysteine 200 mg/mL 30 mL vials are available in limited quantities with a short expiration date (December 2016).

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=932>



## Theophylline Extended-Release Tablets

October 19, 2016

### Reason of Shortage

- Major has discontinued theophylline extended-release tablets.
- Teva cannot provide a reason for the shortage.

### Estimated Resupply Dates

- Teva has theophylline extended-release tablets temporarily unavailable and the company cannot estimate a release date.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1221>

## Sodium Chloride 0.9% Injection Bags

October 19, 2016

### Reason of Shortage

- Baxter discontinued 0.9% sodium chloride 250 mL and 500 mL AVIVA bags. The other presentations are available or on allocation.
- BBraun has 0.9% sodium chloride available for current customers.
- Hospira cites increased demand as the reason for the shortage.
- Fresenius Kabi is no longer importing product.
- 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 0.9% sodium chloride in 1000 mL PVC/DEHP-free bags on allocation.
- BBraun has 0.9% sodium chloride in 250 mL, 500 mL, and 1000 mL PVC/DEHP-free bags on allocation.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=993>

## Ranitidine Injection

October 19, 2016

### Reason of Shortage

- West-Ward discontinued ranitidine injection in September 2014.
- Covis had Zantac on shortage due to capacity issues at the manufacturer.
- IGI laboratories acquired Zantac injection from Covis in October 2015.
- Zydus has temporarily discontinued ranitidine injection due to stability issues.
- Oral ranitidine products are not affected by this shortage.

### Estimated Resupply Dates

- Teligent has Zantac 6 mL vials on back order and the company estimates a release date of December 2016.
- Zydus has temporarily discontinued ranitidine injection.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=820>

### **Mannitol Injection**

**October 19, 2016**

#### **Reason of Shortage**

- American Regent has mannitol injection on shortage due to manufacturing delays.
- Hospira had mannitol injection 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 estimates a release date of late-October to early-November 2016.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=863>

### **Bupivacaine with epinephrine Injection**

**October 19, 2016**

#### **Reason of Shortage**

- Hospira has bupivacaine with epinephrine on shortage due to manufacturing delays.

#### **Estimated Resupply Dates**

- Fresenius Kabi has 0.25% Sensorcaine-MPF with epinephrine 10 mL and 30 mL vials and 0.5% Sensorcaine-MPF with epinephrine 10 mL vials on back order and the company estimates a release date of late-October to early-November 2016.
- Hospira has 0.25% bupivacaine with epinephrine 30 mL vials available in limited supply. The 0.25% bupivacaine with epinephrine 10 mL and 50 mL vials on back order and the company estimates a release date of early-November 2016 for the 10 mL vials and late-December 2016 for the 50 mL vials. The 0.5% bupivacaine with epinephrine 10 mL and 50 mL vials are on back order and the company estimates a release date of early-November 2016 for the 10 mL vials and late-December 2016 for the 50 mL vials. The 30 mL vials are available in limited supply.
- Hospira has 0.25% Marcaine with epinephrine 10 mL vials available in limited supply. The 0.25% Marcaine 30 mL vials are on back order and the company estimates a release date of late-October 2016

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=937>

### **Bupivacaine Injection**

**October 19, 2016**

#### **Reason of Shortage**

- AuroMedics has not provided a reason for the shortage.
- Fresenius Kabi has Sensorcaine on shortage due to increased demand for the product.

- Hospira has bupivacaine on shortage due to manufacturing delays.

**Estimated Resupply Dates**

- AuroMedics has 0.25% bupivacaine 30 mL vials, and 0.5% bupivacaine 30 mL vials on intermittent back order and the company is releasing product as it becomes available.
- Hospira has 0.5% bupivacaine 20 mL ampule sterile packs on back order and the company cannot estimate a release date.
- Hospira has 0.25% Marcaine 50 mL and 0.5% Marcaine 50 mL vials available in limited supply.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=864>

**Amikacin Injection**

**October 19, 2016**

**Reason of Shortage**

- West-Ward launched amikacin injection in 2 mL and 4 mL vials in December 2015.
- Teva has amikacin on shortage due to manufacturing delays. Teva recalled 7 lots in August 2016. The recall details are available on the FDA website.
- Heritage had amikacin injection on shortage due to manufacturing delays.
- Fresenius Kabi launched amikacin in early 2016. Both 2 mL and 4 mL vials are available.

**Estimated Resupply Dates**

- Teva has temporarily discontinued all amikacin presentations and the company cannot estimate a return date.
- West-Ward has amikacin 250 mg/mL 2 mL and 4 mL vials on back order and the company cannot estimate a release date.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1192>

**Dexrazoxane Injection**

**October 21, 2016**

**Reason of Shortage**

- Biocodex USA acquired Totect from Apricus Pharmaceuticals in April 2013.
- Mylan Institutional has dexrazoxane available.
- West-Ward is not actively marketing dexrazoxane injection at this time.

**Estimated Resupply Dates**

- Biocodex USA has not yet started manufacturing Totect and the company cannot estimate when product will be available.
- Pfizer has Zinecard 500 mg vials on back order and the company estimates a release date of 4th quarter 2017.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=415>

## Bleomycin Sulfate Injection

October 21, 2016

### Reason of Shortage

- Fresenius Kabi has bleomycin on back order due to shortage of active pharmaceutical ingredient.
- Hospira has bleomycin on shortage due to increase demand for the product.
- Teva has temporarily discontinued bleomycin.
- FDA is allowing temporary importation of bleomycin sulfate powder for injection 15,000 IU (15 units bleomycin sulfate USP). These vials were manufactured for Amneal Australia. The labeling and bar coding for the imported product is different from the US version. The imported product should be used in the same way as the US product. FDA Dear Healthcare Professional letter. The product should be available to order through major wholesalers.

### Estimated Resupply Dates

- Fresenius Kabi has bleomycin 15 unit vials on allocation. Bleomycin 30 unit vials are on back order and the company estimates a release date of 2nd quarter 2017.
- Hospira has bleomycin 15 unit and 30 unit vials on allocation.
- Teva has bleomycin 15 unit and 30 unit vials on allocation and the company is releasing product regularly.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1233>