



**May 2016**

Drug Information Update

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## NEW GENERICS TO MARKET

GENERIC DRUG NAME	STRENGTH & DOSAGE FORM	GENERIC MANUFACTURER	BRAND NAME	APPROVAL DATE
EMOLLIENT COMBINATION NO.60	Gel w/ pump	Oculus	CELACYN	04/18/2016
FLURANDRENOLIDE	0.05% cream	Cintex Services	CORDRAN	04/20/2016
IBUPROFEN LYSINE/PF	20mg/2ml vial	X-Gen Pharmaceuticals	NEOPROFEN	04/26/2016
QUAZEPAM	15 mg tablet	Thompson	DORAL	04/27/2016
LIDOCAINE HCL	10mg/ml	Pharmedium	LIDOCAINE HCL	05/02/2016
CLINDAMYCIN PHOS/BENZOYL PEROX	1%-5% Gel w/ pump	Perrigo	BENZACLIN	05/02/2016
ROSUVASTATIN	10 mg tablet	Actavis	CRESTOR	05/02/2016
ROSUVASTATIN	20 mg tablet	Actavis	CRESTOR	05/02/2016
ROSUVASTATIN	40mg tablet	Actavis	CRESTOR	05/02/2016
ROSUVASTATIN	5mg tablet	Actavis	CRESTOR	05/02/2016
TRIAMCINOLONE ACETON/SILICONES	0.1% kit	Shoreline Pharmaceuticals	DERMAZONE	05/04/2016

## NEW DRUG ENTITIES

DESCRIPTION	BRAND NAME	GENERIC NAME	STRENGTH	NOTES
Analgesics, Narcotics	Hydromorphone HCl	Hydromorphone HCl	60 mg/30 mL (2 mg/mL)	New Strength
Antimigraine Preparations	Onzetra Xsail	Sumatriptan Succinate	11 mg	New Strength, Route and Dosage Form
Anticonvulsants	Smatrix GABA-V Kit	Gabapentin/Capsi/Me- Sal/Menth	300 mg- 0.037%-20%- 5%	New Combination
Urinary pH Modifiers	Renacidin	Citric Ac/Gluconolact/Mag Carb	6.602 grams- 0.198 grams- 3.268 gram/100 mL	New Combination
Analgesics, Narcotics	Hydromorph-Ropiva- 0.9% NaCl	Hydromorphone/Ropiv/ Sod Chl/PF	8 mcg/mL- 0.1%	New Strength
Topical Anti-Inflammatory Steroidal	Ultravate	Halobetasol Propionate	0.05%	New Dosage Form
NSAIDS, Cyclooxygenase-2 (COX-2) Selective Inhibitor	Capxib	Celecoxib/Capsaicin/Ment hol	200 mg- 0.0375%-5%	New Combination
Antineoplastic Systemic Enzyme Inhibitors	Cabometryx	Cabozantinib S-Malate	20 mg	New Strength and Dosage Form
Antineoplastic Systemic Enzyme Inhibitors	Cabometryx	Cabozantinib S-Malate	40 mg	New Strength and Dosage Form
Antineoplastic Systemic Enzyme Inhibitors	Cabometryx	Cabozantinib S-Malate	60 mg	New Strength and Dosage Form
Analgesics, Narcotics	Xtampza ER	Oxycodone Myristate	9 mg	New Entity
Analgesics, Narcotics	Xtampza ER	Oxycodone Myristate	13.5 mg	New Entity
Analgesics, Narcotics	Xtampza ER	Oxycodone Myristate	18 mg	New Entity
Analgesics, Narcotics	Xtampza ER	Oxycodone Myristate	27 mg	New Entity
Analgesics, Narcotics	Xtampza ER	Oxycodone Myristate	36 mg	New Entity
Selective Serotonin 5- HT2A Inverse Agonists (SSIA)	Nuplazid	Pimavanserin Tartrate	17 mg	New Entity
Rosacea Agents, Topical	Mirvaso	Brimonidine Tartrate	0.33%	New Dosage Form
NSAIDS, Cyclooxygenase-2 (COX-2) Selective Inhibitor	Lidoxib	Celecoxib/Lidocaine/Ment hol	200 mg-4%- 1%	New Combination

## NEW INDICATIONS (EXISTING DRUGS)

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DRUG	NEW INDICATION	DATE OF APPROVAL	LINKS
<b>Gilotrif (afatinib)</b>	Advanced squamous cells carcinoma of the lung	04/15/2016	Gilotrif [package insert] Boehringer Ingelheim. April 2016
<b>ProAir RespiClick (albuterol sulfate) Inhalation Powder</b>	Pediatric Asthma Patients Ages 4 to 11	04/29/2016	ProAir RespiClick [package insert] Teva. April 2016
<b>Fycompa (perampanel) Oral Suspension</b>	Adjunctive Therapy in Treatment of Partial-Onset Seizures and Primary Generalized Tonic-Clonic Seizures	05/02/2016	Fycompa [package insert] Eisai. May 2016

## FDA NEWS/BULLETINS/ADVISORIES/SAFETY ALERTS

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### Metformin-containing Drugs: Drug Safety Communication - Revised Warnings for Certain Patients With Reduced Kidney Function

[Posted 04/08/2016]

**ISSUE:** FDA is requiring labeling changes regarding the recommendations for metformin-containing medicines for diabetes to expand metformin's use in certain patients with reduced kidney function. The current labeling strongly recommends against use of metformin in some patients whose kidneys do not work normally. FDA was asked to review numerous medical studies regarding the safety of metformin use in patients with mild to moderate impairment in kidney function, and to change the measure of kidney function in the metformin drug labeling that is used to determine whether a patient can receive metformin.

FDA concluded, from the review of studies published in the medical literature, that metformin can be used safely in patients with mild impairment in kidney function and in some patients with moderate impairment in kidney function. FDA is requiring changes to the metformin labeling to reflect this new information and provide specific recommendations on the drug's use in patients with mild to moderate kidney impairment.

FDA is also requiring manufacturers to revise the labeling to recommend that the measure of kidney function used to determine whether a patient can receive metformin be changed from one based on a single laboratory parameter (blood creatinine concentration) to one that provides a better estimate of renal function (i.e., glomerular filtration rate estimating equation (eGFR)). This is because in addition to blood creatinine concentration, the glomerular filtration rate takes into account additional parameters that are important, such as the patient's age, gender, race and/or weight. See the FDA Drug Safety Communication for additional information, including a data summary and a list of metformin-containing drugs.

**BACKGROUND:** Metformin-containing medicines are available by prescription only and are used along with diet and exercise to lower blood sugar levels in patients with type 2 diabetes. When untreated, type 2 diabetes can lead to serious problems, including blindness, nerve and kidney damage, and heart disease. Metformin-containing medicines are available as single-ingredient products and also in combination with other drugs used to treat diabetes. The current drug labeling strongly recommends against metformin use in some patients whose kidneys do not work normally because use of metformin in these patients can increase the risk of developing a serious and potentially deadly condition called lactic acidosis, in which too much lactic acid builds up in the blood.

**RECOMMENDATION:** Healthcare professionals should follow the latest recommendations when prescribing metformin-containing medicines to patients with impaired kidney function. Patients should talk to their health care professionals if they have any questions or concerns about taking metformin.

The labeling recommendations on how and when kidney function is measured in patients receiving metformin will include the following information:

- Before starting metformin, obtain the patient's eGFR.
- Metformin is contraindicated in patients with an eGFR below 30 mL/minute/1.73 m<sup>2</sup>.
- Starting metformin in patients with an eGFR between 30-45 mL/minute/1.73 m<sup>2</sup> is not recommended.
- Obtain an eGFR at least annually in all patients taking metformin. In patients at increased risk for the development of renal impairment such as the elderly, renal function should be assessed more frequently.
- In patients taking metformin whose eGFR later falls below 45 mL/minute/1.73 m<sup>2</sup>, assess the benefits and risks of continuing treatment. Discontinue metformin if the patient's eGFR later falls below 30 mL/minute/1.73 m<sup>2</sup>.
- Discontinue metformin at the time of or before an iodinated contrast imaging procedure in patients with an eGFR between 30 and 60 mL/minute/1.73 m<sup>2</sup>; in patients with a history of liver disease, alcoholism, or

heart failure; or in patients who will be administered intra-arterial iodinated contrast. Re-evaluate eGFR 48 hours after the imaging procedure; restart metformin if renal function is stable.

**SOURCE:** U.S. Food and Drug Administration (FDA)

### **Sterile Drug Products from Pharmakon Pharmaceuticals, Inc: CDER Statement - FDA alerts health care professionals not to use due to a lack of sterility assurance and other quality issues**

**[Posted: 4/16/2016]**

**ISSUE:** FDA is alerting health care professionals not to use any drug products that are intended to be sterile and are produced and distributed nationwide by Pharmakon Pharmaceuticals Inc., in Noblesville, Indiana, due to a lack of sterility assurance and other quality issues

**BACKGROUND:** FDA recently inspected Pharmakon's facility following the company's voluntary recall of super-potent morphine sulfate 0.5 mg/ml preservative free in 0.9% sodium chloride, 1 ml syringe, CII, for intravenous use. FDA test results showed the product to be nearly 2,500 percent the labeled potency. During the inspection, investigators observed insanitary conditions, including poor sterile production practices, and other deficiencies, which raise concerns about Pharmakon's ability to assure the sterility and quality of drug products that it produces. Additionally, FDA testing confirmed environmental contamination on multiple sites within the clean rooms, including the critical ISO-5 area.

On April 11, 2016, FDA recommended that Pharmakon cease sterile operations until appropriate corrective actions have been implemented by the facility and recall all non-expired drug products that are intended to be sterile. On April 12, 2016, Pharmakon informed FDA that it would neither initiate a recall nor cease sterile production. Therefore, FDA is alerting health care professionals not to use drug products marketed as sterile from Pharmakon.

**RECOMMENDATION:** Health care professionals should immediately check their medical supplies, quarantine any drug products marketed as sterile from Pharmakon, and not administer them to patients. Administration of a non-sterile drug product intended to be sterile may result in serious and potentially life-threatening infections or death.

**SOURCE:** U.S. Food and Drug Administration (FDA)

### **50% Magnesium Sulfate Injection, USP by Hospira: Recall - Presence Of Particulate Matter**

**[Posted: 04/19/2016]**

Safety Alerts for Human Medical Products > 50 Percent Magnesium Sulfate Injection, USP by Hospira: Recall - Presence Of Particulate Matter

**ISSUE:** Hospira, Inc. is voluntarily recalling one lot of 50% Magnesium Sulfate Injection, USP, 10 g/20 mL (0.5 g/ml), 20 mL Single-dose vials, Lot 50-343-DK, Expiration 01FEB2017, NDC 0409-2168-02, to the hospital level due to a confirmed customer complaint for the presence of particulate matter, within one single-dose fliptop vial. A recall was previously executed for this lot on March 23, 2016 due to a confirmed high out of specification (OOS) result for pH.

If the particulate is detected prior to dispensing or administration to a patient, patient harm is unlikely. If the delay of therapy is prolonged, there is the potential for serious medical consequences for mother and fetus requiring medical intervention. If the particulate is not observed prior to administration, it may result in localized swelling, redness, pain at the site of administration or veins, allergic reactions to the foreign particle, microembolic effects as well as possible fetal harm. The likelihood of serious patient harm is considered low due to high-detectability of

this non-conformance.

**BACKGROUND:** Magnesium Sulfate Injection, USP is suitable for replacement therapy in magnesium deficiency, especially in acute hypomagnesemia accompanied by signs of tetany similar to those observed in hypocalcemia. In total parenteral nutrition, magnesium sulfate may be added to the nutrient admixture to correct or prevent hypomagnesemia which can arise during the course of therapy.

Magnesium Sulfate injection is also indicated for the prevention and control of seizure in pre-eclampsia and eclampsia.

**RECOMMENDATION:** Anyone with an existing inventory of the recalled lot should stop use and distribution and quarantine the product immediately. Inform health care professionals in your organization of this recall. If you have further distributed the recalled product, please notify any accounts or additional locations which may have received the recalled product from you. Further, please instruct entities that may have received the recalled product from you that if they redistributed the product, they should notify their accounts, locations or facilities of the recall to the hospital level. Hospira will be notifying its direct customers via a recall letter and is arranging for impacted product to be returned to Stericycle in the United States.

**SOURCE:** U.S. Food and Drug Administration (FDA)

### **Sensorcaine-MPF (bupivacaine HCl) by Fresenius Kabi: Recall - Presence of Particulate Matter** **[POSTED: 04/26/2016]**

**ISSUE:** Fresenius Kabi USA announced today it is voluntarily recalling a single lot (Lot Number 6111504; Product Code 470237) of Sensorcaine®-MPF (bupivacaine HCl) Injection, USP, 0.75%, 7.5 mg/mL, 30 mL fill in a 30 mL vial. The recall is being performed to the user level due to visible particulate matter characterized as glass observed by the company during inspection of reserve samples. Administration of a solution containing glass particulate matter by the epidural or retrobulbar (behind the eyeball) route may result in inflammation and injury, or cause blockage of vasculature around the eye or emboli in the vasculature of eye nerves. If the particulate goes undetected and solution is administered - depending on the particle size and number - it could block administration of the drug to the patient, causing a delay in therapy. If the particulates are able to pass through the catheter and may result in local inflammation, mechanical disruption of tissue or immune response to the particulate. To date, Fresenius Kabi has not received any reports of adverse events related to this recall.

**BACKGROUND:** Sensorcaine®-MPF (bupivacaine HCl) Injection is indicated for the production of local or regional anesthesia or analgesia for surgery, dental and oral surgery procedures, diagnostic and therapeutic procedures and for obstetrical procedures. The recalled product is labeled with Product Code 470237 and Lot Number 6111504 and is supplied as 0.75% strength in a 30 mL single dose flint molded vial and packaged in units of 25. The product was shipped in the United States to wholesaler and distributor outlets between March 4, 2016 and March 21, 2016 and has an expiration date of September 2019. The NDC number for this product is 63323-472-37.

**RECOMMENDATION:** Fresenius Kabi is notifying its distributors and customers by letter and is arranging for return of all recalled product. If health care facilities have the affected lot, they are to immediately discontinue distributing, dispensing or using the lot and return all units to Fresenius Kabi. Distributors are instructed to immediately notify their customers that have been shipped, or may have been shipped the product involved in this recall and direct them to discontinue distributing, dispensing or using the affected lot and return the product to Fresenius Kabi.

Consumers with questions regarding this recall can contact Fresenius Kabi at 1-800-551-7176 Monday through Friday, during the hours of 8:00 a.m. to 5:00 p.m. or [productcomplaint.USA@fresenius-kabi.com](mailto:productcomplaint.USA@fresenius-kabi.com) or [adverse.events.USA@fresenius-kabi.com](mailto:adverse.events.USA@fresenius-kabi.com). Consumers should contact their physician or healthcare provider if they



have experienced any problems that may be related to taking or using this drug product.

**SOURCE:** U.S. Food and Drug Administration (FDA)

### **Fluconazole (Diflucan): Drug Safety Communication - FDA Evaluating Study Examining Use of Oral Fluconazole (Diflucan) in Pregnancy**

**[POSTED: 04/26/2016]**

**ISSUE:** FDA is evaluating the results of a Danish study that concludes there is a possible increased risk of miscarriage with the use of oral fluconazole (Diflucan) for yeast infections. FDA is also reviewing additional data and will communicate final conclusions and recommendations when the review is complete.

The current FDA drug label states that data available from studies in people do not suggest an increased risk of problems during pregnancy or abnormalities in developing babies when women are exposed to a single 150 mg dose of oral fluconazole to treat vaginal yeast infections. However, high doses of oral fluconazole (400-800 mg/day) taken by pregnant women for much longer than a single dose have resulted in reports of abnormalities at birth. In the Danish study, most of the oral fluconazole use appeared to be one or two doses of 150 mg.

**BACKGROUND:** Oral fluconazole is used to treat yeast infections of the vaginal area, mouth, and esophagus. It is also used to treat a fungal infection of the brain and spinal cord called cryptococcal meningitis that most often affects people with weakened immune systems, and used to prevent yeast infections that can spread to the rest of the body in cancer patients who have a weakened immune system. It is available under the brand name Diflucan and also as generics.

**RECOMMENDATION:** Until FDA's review is complete and more is understood about this study and other available data, FDA advises cautious prescribing of oral fluconazole in pregnancy.

Health care professionals should be aware that the Centers for Disease Control and Prevention guidelines recommend only using topical antifungal products to treat pregnant women with vulvovaginal yeast infections, including for longer periods than usual if these infections persist or recur.

Patients who are pregnant or actively trying to get pregnant should talk to their health care professionals about alternative treatment options for yeast infections.

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 (FDA)

### **BRINTELLIX (VORTIOXETINE): DRUG SAFETY COMMUNICATION - BRAND NAME CHANGE TO TRINTELLIX, TO AVOID CONFUSION WITH ANTIPLATELET DRUG BRILINTA (TICAGRELOR)**

**[POSTED: 05/02/2016]**

**ISSUE:** FDA has approved a brand name change for the antidepressant Brintellix (vortioxetine) to decrease the risk of prescribing and dispensing errors resulting from name confusion with the blood-thinning medicine Brilinta (ticagrelor). The new brand name of the drug will be Trintellix, and it is expected to be available starting in June

2016. No other changes will be made to the label or packaging, and the medicine is exactly the same.

Because of the lag time associated with manufacturing bottles with the new brand name, health care professionals and patients may continue to see bottles labeled with the brand name Brintellix during the transition period.

In a July 2015 MedWatch Alert, FDA warned that name confusion between Brintellix and Brilinta had resulted in prescribing and dispensing errors since Brintellix was approved in September 2013. Due to continued reports of name confusion between the two medicines used for very different purposes, FDA worked with Brintellix manufacturer Takeda Pharmaceuticals to change the drug's brand name.

**BACKGROUND:** Brintellix/Trintellix (vortioxetine) is used to treat a certain type of depression called major depressive disorder in adults. It is in a class of antidepressants called serotonin reuptake inhibitors (SSRIs) that work by affecting chemicals in the brain that may become unbalanced.

**RECOMMENDATION:** Health care professionals should check carefully to make sure they have prescribed or dispensed the correct medicine. During the transition to the new name change from Brintellix to Trintellix, prescribers can reduce the risk of name confusion by including the generic name of the medication they are ordering, in addition to the brand name and indication for use. Patients should make sure they have received the correct medicine. Trintellix tablets will look the same as the Brintellix tablets. Those having any questions or concerns should talk to their prescriber or pharmacist.

Individuals responsible for ordering and stocking the medicine should be aware that Trintellix will have a new National Drug Code (NDC) number. It is important for drug information content publishers and medication-related electronic system administrators to use the new brand name Trintellix and NDC number once Takeda makes vortioxetine available under the new name Trintellix.

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 (FDA)

### **Aripiprazole (Abilify, Abilify Maintena, Aristada): Drug Safety Communication - FDA Warns About New Impulse-control Problems**

**[POSTED: 05/03/2016]**

**ISSUE:** FDA is warning that compulsive or uncontrollable urges to gamble, binge eat, shop, and have sex have been reported with the use of the antipsychotic drug aripiprazole (Abilify, Abilify Maintena, Aristada, and generics). These uncontrollable urges were reported to have stopped when the medicine was discontinued or the dose was reduced. These impulse-control problems are rare, but they may result in harm to the patient and others if not recognized.

Although pathological gambling is listed as a reported side effect in the current aripiprazole drug labels, this description does not entirely reflect the nature of the impulse-control risk FDA identified. In addition, FDA has become aware of other compulsive behaviors associated with aripiprazole, such as compulsive eating, shopping, and sexual actions. These compulsive behaviors can affect anyone who is taking the medicine. As a result, FDA is adding new warnings about all of these compulsive behaviors to the drug labels and the patient Medication Guides for all aripiprazole products.

See the FDA Drug Safety Communication for additional information, including a Data Summary.

**BACKGROUND:** Aripiprazole is used to treat certain mental disorders, including schizophrenia, bipolar disorder, Tourette’s disorder, and irritability associated with autistic disorder. It may also be used in combination with antidepressants to treat depression. Aripiprazole can decrease hallucinations and other psychotic symptoms such as disorganized thinking. It can stabilize mood, improve depression, and decrease the tics of Tourette’s disorder.

**RECOMMENDATION:** Health care professionals should make patients and caregivers aware of the risk of these uncontrollable urges when prescribing aripiprazole, and specifically ask patients about any new or increasing urges while they are being treated with aripiprazole. Closely monitor for new or worsening uncontrollable urges in patients at higher risk for impulse-control problems. These include those with a personal or family history of obsessive-compulsive disorder, impulse-control disorder, bipolar disorder, impulsive personality, alcoholism, drug abuse, or other addictive behaviors. Consider reducing the dose or stopping the medicine if such urges develop.

Patients and caregivers should be alert for uncontrollable and excessive urges and behaviors while taking aripiprazole. It is important to talk with a health care professional as soon as possible if you or a family member experiences any of these uncontrollable urges, in order to prevent or limit possible harm. Patients should not suddenly stop taking their aripiprazole medicine without first talking to their health care professional.

See the FDA Drug Safety Communication for additional information for patients, caregivers, and health care professionals.

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 (FDA)

**The MedWatch March 2016 Safety Labeling Changes posting includes 35 products with safety labeling changes to the following sections: CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, and ADVERSE REACTIONS.**

**[UPDATED: 5/6/2016]**

Key to summary table below: BW=BOXED WARNING, C=CONTRAINDICATIONS, W=WARNINGS, P=PRECAUTIONS  
AR=ADVERSE REACTIONS, PPI/MG=PATIENT PACKAGE INSERT/MEDICATION GUIDE

DRUG NAME	SECTIONS MODIFIED					
	BW	C	W	P	AR	PPI/MG
Invega (paliperidone) Extended-Release Tablets <i>*Contraindication: hypersensitivity</i>		X				
Invega Sustenna (paliperidone palmitate) Extended-release Injectable Suspension <i>*Contraindication: hypersensitivity</i>		X				
Invega Trinza (paliperidone palmitate) Extended-release		X				

Injectable Suspension <i>*Contraindication: hypersensitivity</i>						
Invokamet (canagliflozin and metformin hydrochloride) Tablets		X	X	X	X	
Invokana (canagliflozin) Tablets		X	X	X	X	
PLASMA-LYTE 56 and 5% Dextrose Injection		X		X		
Renagel (sevelamer hydrochloride) Tablets		X			X	
Renvela (sevelamer carbonate) Powder for Oral Suspension		X			X	
Risperdal (risperidone) Tablets, Oral Solution and Risperdal M-TAB (risperidone) Orally Disintegrating Tablets <i>*Contraindication: hypersensitivity</i>		X				
Risperdal Consta (risperidone) Long Acting Injection <i>*Contraindication: hypersensitivity</i>		X				
Tudorza Pressair (aclidinium bromide inhalation powder)		X	X	X	X	
	<b>BW</b>	<b>C</b>	<b>W</b>	<b>P</b>	<b>AR</b>	<b>PPI/MG</b>
Adcetris (brentuximab vedotin) for Injection			X	X		
Angiomax (bivalirudin) Lyophilized Powder for Injection			X	X	X	
Droxia (hydroxyurea) and Hydrea (hydroxyurea) Capsules			X	X	X	
Faslodex (fulvestrant) Solution for Injection			X	X		
Herceptin (trastuzumab) Intravenous Infusion			X	X	X	
Implanon (etonogestrel) Implant			X	X	X	
Jakafi (ruxolitinib phosphate) Tablet			X	X		
Juxtapid (lomitapide) Capsules			X	X		
Nexplanon (etonogestrel) Implants			X	X	X	
Oxytrol for Women (oxybutynin) Transdermal System			X			
Truvada (emtricitabine/tenofovir disoproxil fumarate) Tablets			X	X		
Xgeva (denosumab, AMG 162; Human Monoclonal Antibody to RANK Ligand)			X	X	X	
Zarxio (filgrastim-sndz)			X	X	X	
	<b>BW</b>	<b>C</b>	<b>W</b>	<b>P</b>	<b>AR</b>	<b>PPI/MG</b>
Furosemide Tablets, Injection and Lasix (furosemide)				X		

Tablets						
Genvoya (elvitegravir, cobicistat, emtricitabine, and tenofovir alafenamide) Fixed-dose Combination Tablet				X		
Klonopin (clonazepam) Tablets				X		
Prezcobix (darunavir and cobicistat) Tablet				X		
Sustiva (efavirenz) Capsules and Tablets				X		
	<b>BW</b>	<b>C</b>	<b>W</b>	<b>P</b>	<b>AR</b>	<b>PPI/MG</b>
Cleocin HCl (clindamycin hydrochloride) Capsules					X	
Cleocin Phosphate (clindamycin) Injection and (clindamycin injection in 5% dextrose) Solution in Galaxy Plastic Containers					X	
Increlex (mecasermin [rDNA origin] injection)					X	
Jetrea (ocriplasmin intravitreal) Injection					X	
Zaltrap (ziv-aflibercept) Injection					X	
Zometa (zoledronic acid) Injection					X	

## STUDIES and RECENT TOPICS

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### FDA Panel Backs Approval of Liver-Disease Drug

April 7, 2016

A U.S. Food and Drug Administration advisory panel recommended the agency approve a new drug for the treatment of a rare liver condition—the latest milestone in a rapidly growing market for liver-disease drugs.

**SOURCE:** wsj.com

### Federal Reclassification of Marijuana Could Have Major Impact on Medical Uses

April 11, 2016

Federal authorities have announced that they are reviewing the possibility of loosening the classification of marijuana, and if this happens, it could have a far-reaching impact on how the substance is used in medical settings, experts said.

Marijuana is currently classified as a Schedule I drug, meaning it is listed alongside heroin and LSD as among the "most dangerous drugs" and has "no currently accepted medical use and a high potential for abuse."

**SOURCE:** abcnews.go.com

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

April 12, 2016

Men who take hormone therapy for prostate cancer may have a higher risk of depression 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

### Why It's Getting Harder To Decide When To Treat High Blood Pressure

April 13, 2016

Are you ready for some more uncertainty about blood pressure treatment?

Decisions about blood pressure have gotten more difficult over the past couple of years as experts in the U.S. have failed to reach consensus on recommendations about when drug therapy should be started. Now there's new evidence that could make the decisions even more challenging.

**SOURCE:** npr.org

### The dark side of antioxidants: Fresh evidence that they fuel cancer's spread

April 13, 2016

Research has been increasingly challenging the conventional health food-store wisdom about antioxidants — that they can prevent cancer, slow aging, and work all sorts of other miracles. Now, a study published on Wednesday supports the idea that antioxidants can fuel the spread of cancer cells. Scientists in China and the United States found that two popular drugs for type 2 diabetes, both of which happen to be antioxidants, goose cancer metastasis in lab mice.

**SOURCE:** statnews.com

### Cancer drug labels rarely reflect patient experiences

April 14, 2016

Information about the benefits and drawbacks patients experienced when taking a new cancer drug is rarely included on the product label, even though it could help doctors and patients make treatment choices, researchers say.

**SOURCE:** bizjournals

### Popular medications linked to higher risk of kidney failure

April 16, 2016

Taking one of the most-prescribed medications in the world -- proton pump inhibitors -- might dramatically increase a person's risk for kidney failure and kidney disease, new research suggests. The study was released Thursday in the Journal of the American Society of Nephrology.

**SOURCE:** cnn.com

### 3 Key Aspects of Updated Daily Aspirin Use Guidelines

April 18, 2016

The US Preventive Services Task Force (USPSTF) recently updated its recommendations regarding daily aspirin use as primary prevention for cardiovascular disease (CVD) and colon cancer.

The guidelines published online in the Annals of Internal Medicine updated the USPSTF's 2009 recommendations on aspirin use to prevent CVD events and 2007 recommendations on aspirin and nonsteroidal anti-inflammatory drug (NSAID) use to prevent colon cancer.

**SOURCE:** pharmacytimes.com

## Diabetes Prevalence Has Nearly Quadrupled Since 1980

April 19, 2016

The number of adults living with diabetes worldwide has nearly quadrupled from 108 million in 1980 to 422 million in 2014. The World Health Organization (WHO) recently released its

“Global Report on Diabetes,” which emphasized a greater need for global attention, prevention, and treatment options for patients with diabetes.

**SOURCE:** pharmacytimes.com

## Study finds factors that may influence influenza vaccine effectiveness

April 19, 2016

The long-held approach to predicting seasonal influenza vaccine effectiveness may need to be revisited, new research suggests. Currently, seasonal flu vaccines are designed to induce high levels of protective antibodies against hemagglutinin (HA), a protein found on the surface of the influenza virus that enables the virus to enter a human cell and initiate infection. New research conducted by scientists at the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health, found that higher levels of antibody against a different flu surface protein—neuraminidase (NA)—were the better predictor of protection against flu infection and its unpleasant side effects. Neuraminidase, which is not currently the main target antigen in traditional flu vaccines, enables newly formed flu viruses to exit the host cell and cause further viral replication in the body.

**SOURCE:** medicalxpress.com

## Novartis' Afinitor reduces seizures in TSC patients

April 20, 2016

Novartis' Afinitor has significantly reduced treatment-resistant seizures in patients with tuberous sclerosis complex (TSC) taking part in the Phase III EXIST-3 trial.

TSC is a rare genetic disorder affecting up to one million people worldwide, and Afinitor (everolimus) is the only approved non-surgical option indicated for treating non-cancerous brain and kidney tumours in certain patients with the condition.

**SOURCE:** pharmatimes.com

## Breast cancer drug Herceptin increases heart damage risk, study says

April 20, 2016

Although doctors already monitor older breast cancer patients for heart damage if their treatment includes the drug trastuzumab, researchers suggest all patients on the drug should be monitored based on the results of a recent study.

Researchers in Canada report in a study, published in the Journal of Clinical Oncology, that the drug significantly increased the risk for major cardiac events among all patients, regardless of age.

**SOURCE:** upi.com



### Aspirin may prolong survival for cancer patients by up to a fifth

April 21, 2016

It has been hailed a "wonder drug" because of its numerous health benefits, and now, a new study provides further evidence that aspirin may help in the fight against cancer.

Published in the journal PLOS One, the study suggests that taking low doses of aspirin may increase survival for cancer patients by up to a fifth, as well as reduce the spread of the disease.

**SOURCE:** medicalnewstoday.com

### No Link Between Anti-Smoking Drugs, Mental Health Issues: Study

April 22, 2016

The anti-smoking drugs Chantix (varenicline) and Wellbutrin (bupropion) don't appear to raise the risk of serious mental health disorders such as depression, anxiety and suicidal thoughts, a new study suggests. "Clinical guidelines recommend that the most effective way to give up smoking is smoking cessation medication and counseling. However, smokers do not use these services enough, in part due to concerns that the medications may not be safe," said lead author Dr. Robert Anthenelli, professor of psychiatry at University of California, San Diego.

**SOURCE:** healthday.com

### More evidence links heartburn drugs to serious kidney problems

April 22, 2016

People taking common heartburn medications known as proton pump inhibitors (PPIs) are at increased risk of new and severe kidney disease, according to a U.S. study. Among hundreds of thousands of patients in Department of Veterans Affairs (VA) databases, new users of PPIs without kidney disease were 30 percent more likely to develop chronic kidney disease over the course of five years. Their risk of kidney failure was doubled.

**SOURCE:** reuters.com

### FDA and WHO warn about clinical trials run by an Indian company

April 25, 2016

The US Food and Drug Administration last week alerted an untold number of drug makers that marketing applications containing clinical trial data prepared by an Indian contract research organization would not be accepted due to concerns about the integrity of the data.

**SOURCE:** statnews.com

### Pharmacists Can Manage Some Chronic Conditions Effectively, Study Suggests

April 25, 2016

Pharmacists may do a better job than doctors helping chronically ill patients manage their blood pressure, cholesterol and blood sugar levels if they're allowed to direct people's health care, a new evidence review suggests.

The review also found that pharmacists could manage chronic diseases with about the same efficiency as doctors.

**SOURCE:** healthday.com

### Researchers find four supplements that boost efficacy of antidepressants

**April 26, 2016**

PARKVILLE, Australia - An international evidence review has found that certain nutritional supplements can increase the effectiveness of antidepressants for people with clinical depression.

Omega 3 fish oils, S-adenosylmethionine (SAME), methylfolate (bioactive form of folate) and vitamin D, were all found to boost the effects of medication.

**SOURCE:** drugstorenews.com

### FDA may approve implantable drug to ease opioid withdrawal

**May 2, 2016**

A drug that has shown success in helping opioid addicts control their dependence on heroin and painkillers soon could see increased use by patients and adoption by doctors if federal authorities approve a new delivery method for the medication.

**SOURCE:** cnbc.com

### Getting High From This Drug For Diarrhea Can Be Fatal

**May 3, 2016**

Some people addicted to oxycodone and other opioids are now turning to widely available diarrhea medications to manage their withdrawal symptoms or get high.

The results can be dangerous to the heart — and sometimes fatal — warn toxicologists in a study recently published online in the Annals of Emergency Medicine.

**SOURCE:** npr.org

### Study: Patients paying less for painkillers

**May 3, 2016**

The cost of prescription painkillers has been gradually decreasing for patients, with a growing share of the costs now covered by insurers, according to new research.

That shift over the last decade could be partly responsible for the dramatic increase in the use of the powerful, and increasingly deadly, drugs, according to a study published Monday in the journal Health Affairs.

**SOURCE:** thehill.com

## CDC warns that Americans may be overmedicating youngest children with ADHD

May 3, 2016

U.S. health officials are urging parents of preschoolers with attention-deficit/hyperactivity disorder (ADHD) to try behavior therapy first before trying drugs — and they're calling on insurers to cover the treatments.

The concern comes from new statistics that show a troubling gap between recommended practices for treating the youngest Americans and what's happening on the ground at doctors' offices. The Centers for Disease Control and Prevention recommends that parents of young children with the diagnosis try behavior therapy first, but less than half are receiving such services. Meanwhile, an eyebrow-raising 75 percent are receiving drugs as treatment.

**SOURCE:** [washingtonpost.com](http://washingtonpost.com)

## RECALLS\*

Product Type	Product Description	Code Info	Class	Reason for Recall	Recalling Firm
<b>CLASS I</b>					
Drugs			Class I		
<b>CLASS II</b>					
Drugs	Cisatracurium Besylate Injection, 20 mg per 10 mL (2 mg per mL), For intravenous injection, 10 mL Multiple Dose Vial NDC 63323-417-10	Lot #: 6010157, Exp. 01/2017	Class II	Incorrect/ Undeclared Excipient: Firm is recalling product due to an incorrect statement of Preservative free on the individual carton label. The vial label and outer carton label contain the correct statement of 0.9% benzyl alcohol added as a preservative.	Fresenius Kabi USA, LLC 3 Corporate Dr Lake Zurich, IL 60047-8930
Drugs	Dextroamphetamine Saccharate, Amphetamine Aspartate, Dextroamphetamine Sulfate, and Amphetamine Sulfate Tablets, 5 mg, 100 ct. bottle. NDC: 45963-743-11.	Lot #: 2172#141, Expiry: 3/16; Lot #: 4217K141, Expiry: 3/16; Lot #: 0420A151, Expiry: 7/16; Lot #: 0421A151, Expiry: 7/16; Lot #: 0854B151, Expiry: 10/16; Lot #: 1329C151, Expiry: 10/16; Lot #: 2692F151, Expiry: 2/17; Lot #: 3202G151, Expiry: 3/17; Lot #: 3796J151, Expiry: 3/17; Lot #: 3797J151, Expiry: 4/17.	Class II	Failed Impurities/Degradation Specifications: Out of specification for impurities.	Actavis Elizabeth LLC 200 Elmora Ave Elizabeth, NJ 07202-1106
Drugs	Dextroamphetamine Saccharate, Amphetamine Aspartate, Dextroamphetamine Sulfate, and Amphetamine Sulfate Tablets, 10 mg, 100 ct. bottle. NDC: 45963-745-11.	Lot #: 2172#141, Expiry: 3/16; Lot #: 4217K141, Expiry: 3/16; Lot #: 0420A151, Expiry: 7/16; Lot #: 0421A151, Expiry: 7/16; Lot #: 0854B151, Expiry: 10/16; Lot #: 1329C151, Expiry: 10/16; Lot #: 2692F151, Expiry: 2/17; Lot #: 3202G151,	Class II	Failed Impurities/Degradation Specifications: Out of specification for impurities.	Actavis Elizabeth LLC 200 Elmora Ave Elizabeth, NJ 07202-1106

Product Type	Product Description	Code Info	Class	Reason for Recall	Recalling Firm
		Expiry: 3/17; Lot #: 3796J151, Expiry: 3/17; Lot #: 3797J151, Expiry: 4/17.			
Drugs	Dextroamphetamine Saccharate, Amphetamine Aspartate, Dextroamphetamine Sulfate, and Amphetamine Sulfate Tablets, 20 mg, 100 ct. bottle, NDC: 45963-748-11.	Lot #: 3992J141, Expiry: 5/16; Lot #: 3993J142, Expiry: 5/16; Lot #: 0695B151, Expiry: 7/16; Lot #: 0696B151, Expiry: 7/16; Lot #: 0378A151, Expiry: 7/16; Lot #: 0379A151, Expiry: 7/16; Lot #: 0697B151, Expiry: 8/16; Lot #: 2427F151, Expiry: 11/16; Lot #: 1947E151, Expiry: 11/16; Lot #: 1330C151, Expiry: 11/16; Lot #: 1331C151, Expiry: 11/16; Lot #: 1946E151, Expiry: 11/16; Lot #: 3652H151, Expiry: 2/17; Lot #: 3653H151, Expiry: 3/17, Lot #: 3654H151, Expiry: 3/17; Lot #: 4251K151, Expiry: 3/17; Lot #: 4250K151, Expiry: 4/17; Lot #: 4252K151, Expiry: 4/17; Lot #: 4249K151, Expiry: 4/17; Lot #: 5101M151, Expiry: 5/17.	Class II	Failed Impurities/Degradation Specifications: Out of specification for impurities.	Actavis Elizabeth LLC 200 Elmora Ave Elizabeth, NJ 07202-1106
Drugs	Dextroamphetamine Saccharate, Amphetamine Aspartate, Dextroamphetamine Sulfate, and Amphetamine Sulfate Tablets, 30 mg, 100 ct. bottle, NDC: 45963-749-11.	Lot #: 1879E141, Expiry 02/16; Lot #: 1880E141, Expiry: 02/16; Lot #: 5034M142; Expiry: 5/16; Lot #: 0422A151, Expiry: 7/16; Lot #: 0423A151, Expiry: 7/16; Lot #: 1053C151, Expiry: 8/16; Lot #: 1054C151, Expiry: 8/16; Lot #: 2197E152, Expiry: 11/16; Lot #: 2198E151, Expiry: 12/16; Lot #: 2662F151, Expiry: 12/16; Lot #: 2672F152, Expiry: 3/17; Lot #: 3121G152, Expiry: 3/17; Lot #: 3798J151, Expiry: 4/17; Lot #: 5104M151,	Class II	Failed Impurities/Degradation Specifications: Out of specification for impurities.	Actavis Elizabeth LLC 200 Elmora Ave Elizabeth, NJ 07202-1106

Product Type	Product Description	Code Info	Class	Reason for Recall	Recalling Firm
		Expiry: 5/17.			
Drugs	Formula 2 (Papaverine 9 mg, Phentolamine 1 mg, Atropine 0.1 mg, PGE 10 mcg/mL) Injection, 5 mL vials	Lot #: 110115-2, Exp 01/01/16	Class II	Superpotent Drug: one ingredient was found to be above assay specification.	Meditech Laboratories, Inc 3200 Polaris Ave Ste 27 Las Vegas, NV 89102-8379
Drugs	Formula 4 (Papaverine 18 mg, Phentolamine 2 mg, Atropine 0.2 mg/mL) Injection, 5 mL vials	Lot#: 022316-4, Exp 04/08/16	Class II	Lack of Assurance of Sterility: incomplete or missing data regarding production.	Meditech Laboratories, Inc 3200 Polaris Ave Ste 27 Las Vegas, NV 89102-8379
Drugs	Formula 9 (Papaverine 0.9 mg, Phentolamine 0.1 mg, Atropine 0.01 mg, PGE 20 mcg/mL) Injection, 5 mL vial	Lot#: 022416-9, Exp 04/09/16.	Class II	Lack of Assurance of Sterility: incomplete or missing data regarding production.	Meditech Laboratories, Inc 3200 Polaris Ave Ste 27 Las Vegas, NV 89102-8379
Drugs	Formula 1 (Papaverine 1.8 mg, Phentolamine 0.2 mg, Atropine 0.02 mg, PGE 18 mcg/mL) Injection, 5 mL vial	Lot#: 011916-1, Exp 04/19/16; 020316-1, Exp 05/03/16	Class II	Stability Does Not Support Expiry: manufactured with an active ingredient that expired before the labeled Beyond Use Date.	Meditech Laboratories, Inc 3200 Polaris Ave Ste 27 Las Vegas, NV 89102-8379
Drugs	Formula 3 (Papaverine 20 mg, Phentolamine 3 mg, Atropine 0.2 mg, PGE 20 mcg/mL) Injection, 5 mL vials	Lot#: 011716-3, Exp 04/17/16; 012416-3, Exp 04/24/16.	Class II	Stability Does Not Support Expiry: manufactured with an active ingredient that expired before the labeled Beyond Use Date.	Meditech Laboratories, Inc 3200 Polaris Ave Ste 27 Las Vegas, NV 89102-8379
Drugs	Formula 0 (PGE 20 mcg/mL) Injection, 5 mL vials	Lot#: 020716-0, Exp 05/07/16	Class II	Lack of Assurance of Sterility: incomplete or missing data regarding production.	Meditech Laboratories, Inc 3200 Polaris Ave Ste 27 Las Vegas, NV 89102-8379
Drugs	Formula 2 (Papaverine 9 mg, Phentolamine 1 mg, Atropine 0.1 mg, PGE 10 mcg/mL), 5 mL	Lot #: 12216-2, Exp 04/22/16	Class II	Stability Does Not Support Expiry: manufactured	Meditech Laboratories, Inc 3200 Polaris Ave Ste

Product Type	Product Description	Code Info	Class	Reason for Recall	Recalling Firm
	vials			with an active ingredient that expired before the labeled Beyond Use Date.	27 Las Vegas, NV 89102-8379
Drugs	Dextrose Injection, USP, 70%, Packaged as 500 mL in 1000 mL Bag, NDC 0409-7918-19	Lot# 48-010-JT, Exp 12/16	Class II	Chemical Contamination: Potential for contamination of the products with an aromatic hydrocarbon resin	Hospira Inc. 275 N Field Dr Lake Forest, IL 60045-2579
Drugs	Dextrose Injection, USP, 50%, Packaged as 500 mL in 1000 mL Bag, NDC 0409-7936-19	Lot # 52-002-JT, Exp 04/17	Class II	Chemical Contamination: Potential for contamination of the products with an aromatic hydrocarbon resin	Hospira Inc. 275 N Field Dr Lake Forest, IL 60045-2579
Drugs	Dextrose Injection, USP, 20%, Packaged as 500 mL in 1000 mL Bags, NDC 0409-7935-19	Lot# 52-114-JT, Exp 10/16	Class II	Chemical Contamination: Potential for contamination of the products with an aromatic hydrocarbon resin	Hospira Inc. 275 N Field Dr Lake Forest, IL 60045-2579
Drugs	Aminosyn-PF (amino acids) 7%, Sulfite-Free, 500 mL Bags, NDC: 0409-4178-03	Lot# 49-047-JT, Exp: 07/16		Chemical Contamination: Potential for contamination of the products with an aromatic hydrocarbon resin	Hospira Inc. 275 N Field Dr Lake Forest, IL 60045-2579
Drugs	Mannitol I.V., 20%, USP (20 g/ 100 mL), Packaged in 250 mL Bags, NDC: 0409-7715-02	Lot# 52-031-JT, Exp 10/16		Chemical Contamination: Potential for contamination of the products with an aromatic hydrocarbon resin.	Hospira Inc. 275 N Field Dr Lake Forest, IL 60045-2579
Drugs	Potassium Chloride Injection 20 mEq, 400 mEq/L, Packaged in 50 mL Bags, NDC 0409-7077-14	Lo# 53-006-JT, Exp 11/16		Chemical Contamination: Potential for contamination of the products with an aromatic hydrocarbon resin.	Hospira Inc. 275 N Field Dr Lake Forest, IL 60045-2579

Product Type	Product Description	Code Info	Class	Reason for Recall	Recalling Firm
Drugs	Dextroamphetamine Sulfate Tablets USP, 10 mg, 100-count bottle, NDC 64720-0216-10	Lot # 112579, 112580, Exp 03/17; 111013A, Exp 04/16; 111014, Exp 05/16; 113292, 113332, 113386, 113387, Exp 07/17; 111671,111673, Exp 09/16; 113806, 113807, Exp 10/17; 111874, 111875, 111876, Exp 11/16		Failed Impurities/Degradation Specifications	Impax Laboratories, Inc. 215 Wood Ave Middlesex, NJ 08846-2554
Drugs	Dextroamphetamine Sulfate Tablets USP, 5 mg, 100-count bottle, NDC 64720-215-10	Lot #: 112565, Exp 03/17; 113458, Exp 08/17		Failed Impurities/Degradation Specifications	Impax Laboratories, Inc. 215 Wood Ave Middlesex, NJ 08846-2554
Drugs	Good Neighbor Pharmacy PEG-Phen Lubricant Eye Drops (Polyethylene Glycol 400 0.4% / Propylene Glycol 0.3%), 15 ml bottle, NDC 68016-0404-00	Good Neighbor Pharmacy Batch Number 4H76A; Exp 07/16 Premier Value Batch Number 4H76B; Exp 07/16		Presence of Particulate Matter	Akorn, Inc. 1925 W Field Ct Ste 300 Lake Forest, IL 60045-4862
Drugs	Oxycodone Hydrochloride Oral Solution, USP 5 mg/5 mL (1mg/ml) (NDC 66689-401-01), shrink- wrapped in 10 unit dose cups x 5 trays per case (NDC 66689-401-50),	Lot # 435200, EXP 01/18		Defective Container: Excess lidding material accumulation between the seal and the cup resulting in the lid not properly adhering and allowing leakage.	VistaPharm, Inc. 7265 Ulmerton Rd Largo, FL 33771-4809
<b>CLASS III</b>					
Drugs	Fenofibrate Capsules (Micronized) 134 mg, 500-count bottle NDC 0115-0522-02	Lot # 10008624, 10008831; Exp. 10/16 Lot # 10009339; Exp. 02/17 Lot # 10009566,10009627; Exp. 04/17 Lot # 10010200, 20001419A, 20001426A; Exp. 10/17 Lot # 20001732A; Exp. 04/18 Lot # 20001790A, 20001791A, 20001792A; Exp. 05/18	Class III	Labeling: Incorrect or Missing Lot and/or Exp. Date	Labeling: Incorrect or Missing Lot and/or Exp. Date
Drugs	Fenofibrate Capsules (Micronized) 200 mg, 500-count bottle NDC 0115-0533-	Lot # 10008320; Exp. 05/16 Lot # 10008744, 10008974; Exp. 11/16 Lot	Class III	Labeling: Incorrect or Missing Lot	Impax Laboratories, Inc. 31153 San Antonio



Product Type	Product Description	Code Info	Class	Reason for Recall	Recalling Firm
	02	# 10009342; Exp. 03/17 Lot # 10010202; Exp. 09/17 Lot # 20001416A; Exp. 10/17 Lot # 20001557A; Exp. 01/18 Lot # 20001675A; Exp. 03/18 Lot # 20001831A; Exp. 06/18		and/or Exp. Date	Street Hayward, CA 94544
Drugs	Haloperidol Decanoate Injection, 50 mg/mL, 1 mL vial NDC 63323-469-01	Lot #: 6111080, Exp. 01/2017	Class III	Failed Impurities/Degradation Specifications: Firm is recalling product due to an impurity out-of-specification result.	Fresenius Kabi USA, LLC 3 Corporate Dr Lake Zurich, IL 60047-8930
Drugs	Simvastatin Tablets, USP 5 mg Rx only, a) 90 count (NDC 24658-0300-90) and b) 1000 count (NDC 24658-0300-10) bottles	Lot # 14S0042F5B, exp. 4/2016	Class III	Subpotent Drug	Biocon Inc 485 US Highway 1 S Ste B305 Iselin, NJ 08830-3009
Drugs	Fenofibrate Capsules (Micronized), 134 mg Capsules, 20-count Unit Dose Blister Packs per carton Carton of 20: NDC 68084-835-32, Individual Dose: NDC 68084-835-33.	Lot #144332C; Exp. 04/16 Lot #155224; Exp. 05/17	Class III	Labeling: Incorrect or Missing Lot and/or Exp Date	Amerisource Health Services 2550 John Glenn Ave Suite A Columbus, OH 43217-1188
Drugs	Fenofibrate Capsules (Micronized), 200 mg, 30-count Unit Dose Blister Packs per carton, Rx Only, Packaged and Distributed by: American Health Packaging Columbus, Ohio 43217; Carton of 30: NDC 68084-835-32, Individual Dose: NDC 68084-835-33	Lot #142548; Exp. 05/16 Lot #145036; Exp. 10/16 Lot #151170; Exp. 03/17 Lot #152978; Exp. 09/17 Lot #155080; Exp. 01/18.	Class III	Labeling: Incorrect or Missing Lot and/or Exp Date	Amerisource Health Services 2550 John Glenn Ave Suite A Columbus, OH 43217-1188
Drugs	Ranitidine Syrup (Ranitidine Oral Solution, USP), 15 mg/mL (75 mg/5 mL), 16 fl oz Bottle, NDC 23155-291-51	Lot #: 14G008, 14G013, 14G010, 14G015, 14G016, 14G021, 14G026, 14G028, Exp. 01/2016; 14K027,	Class III	Failed Impurities/Degradation Specifications: Product recalled	Bio-pharm, Inc. 2091 Hartel Ave Levittown, PA 19057-4506

Product Type	Product Description	Code Info	Class	Reason for Recall	Recalling Firm
		14K023, Exp. 04/2016; 15B040, 15B041, Exp. 08/2016; 15E042, Exp. 11/2016; 15F019, 15F021, Exp. 12/2016; 15G038, Exp. 01/2017; 15H004, 15H008, Exp. 02/2017		due to elevated impurity result detected during routine stability testing.	
Drugs	VP-CH-PNV PRENATAL/POSTNATAL Prescription Folic Acid- Containing Dietary Supplement, 30-count Softgel bottles, NDC 69543-224-30	Lot #21506132; Exp. 05/17	Class III	Defective Delivery System: Product may contain leaking capsules.	Virtus Pharmaceuticals, LLC 2649 Causeway Center Dr Tampa, FL 33619- 6102
Drugs	Minocycline Hydrochloride Capsules USP, 100 mg*, 30 Capsules (3 x 10) Unit Dose blisters (NDC 50268-569-11); per carton (NDC 50268-569- 13)	Outer Cases and Cartons Lot #: 13650, EXP 06/2017; Blisters Lot #: 13560, EXP 06/2017	Class III	Labeling: Incorrect or Missing Lot and/or Exp Date: the individual blisters are mis-labeled with an incorrect lot number of 13560 rather than the correct lot number of 13650.	Apac KY LLC 12954 Fountain Run Rd Fountain Run, KY 42133-7914
Drugs	SODIUM IODIDE I 131 CAPSULE, USP DIAGNOSTIC ORAL , NDC 65174-461-05	Lot Number 1670123; Exp 04/16	Class III	Labeling: Label Error on Declared Strength	Jubilant Draximage Inc 16751 Rte Trans- Canada Kirkland
Drugs	Intermezzo (zolpidem tartrate) sublingual tablet 1.75 mg, CIV, 30 Ct Cartons. NDC: 59011-256-30.	Lot #: 3126431B, Expiry: 09/30/17	Class III	Failed Dissolution Specifications	Purdue Pharma L.P. 201 Tresser Blvd Stamford, CT 06901- 3435
Drugs	Telmisartan Tablets, USP, 80 mg, 30-count (3 x 10 unit- dose blisters) per carton, NDC 13668-158-72, UPC 3 13668 158 72 4.	Lot#: BBV8B002R, Exp 12/16	Class III	Presence of Foreign Substance: Product complaint for the presence of foreign matter identified as silicone within the	Torrent Pharmaceuticals Limited Ahmedabad Mehsana Highway Kadi

Product Type	Product Description	Code Info	Class	Reason for Recall	Recalling Firm
				tablet	
Drugs	Zemplar (paricalcitol) capsules, 1 mcg, 30-count bottle, NDC 0074-4317-30	Lot #1055586, Exp.1/21/2018	Class III	Failed Content Uniformity Specifications	AbbVie Inc. 1 N Waukegan Rd North Chicago, IL 60064-1802
Drugs	SKY Aspirin Chewable Tablets, 81 mg, Unit Dose 750 tablets (25 x 30) box, NDC 63739-434-01.	Lot 0110701	Class III	Labeling: Label mix-up -outer carton incorrectly labeled as aspirin chewable tablets.	Mckesson Packaging Services 7101 Weddington Rd NW Concord, NC 28027-3412
Drugs	Quelicin (Succinylcholine Chloride) Injection, USP 200 mg. (20 mg/mL), 10 mL Multiple-dose vial, packaged in 25 Unit vials per carton, NDC 0409-6629-02	Lot 52-045-EV, Exp 07/1/2016	Class III	Labeling: Incorrect or Missing Lot and/or Exp Date: Potential for the lot number and/or expiration date to be faded or missing from the primary label on the glass vial.	Hospira Inc. 275 N Field Dr Lake Forest, IL 60045-2579
Drugs	Venlafaxine 75 mg Tablet, Compare to Effexor 75 mg Tablet, a) 30-count bottle (NDC 636290-3324-2), b) 100-count bottle (NDC 63629-3324-6)	Lot # 94983; Exp 10/17	Class III	Labeling: Label Mix-Up: Bryant Ranch received Tevas venlafaxine hydrochloride extended-release tablets for repackaging, but labeled it incorrectly as the immediate release formulation.	Bryant Ranch Prepack Inc. 1919 N Victory Pl Burbank, CA 91504-3425
Drugs	Acetaminophen & Codeine Phosphate Tablets, 300 mg/30 mg, 15-count plastic bottle, NDC 54569-8305-0	Lot # 6050129, Exp 05/31/17	Class III	Labeling: Not elsewhere classified - count on the label was incorrect.	A-S Medication Solutions LLC. 2401 Commerce Dr Libertyville, IL 60048-4464
<b>BIOLOGICS</b>					
none					

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

## CURRENT DRUG SHORTAGES

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### Octreotide Injection

April 14, 2016

#### Reason for the 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

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

### Mupirocin Calcium 2% cream

April 14, 2016

#### Reason of the Shortage

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

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

### Milrinone Injection

April 14, 2016

#### Reason of the Shortage

- Fresenius Kabi states the reason for the shortage was increased demand for the product.
- Hospira had milrinone injection on shortage due to increased demand.
- West-Ward states the shortage is due to manufacturing delays

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=741#sthash.gv8x65kt.dpuf>

### Mannitol Injection

April 14, 2016

#### Reason of the Shortage

- American Regent has mannitol injection on shortage due to manufacturing delays.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=863#sthash.bwooxy2l.dpuf>

### Clindamycin Injection

April 14, 2016

#### Reason of the Shortage

- Akorn cannot provide a reason for the shortage.
- Pfizer states the Cleocin Add-Vantage vials are on shortage due to manufacturing delays.
- Hospira divested clindamycin injection to Alvogen in September 2015. Alvogen will sell Hospira labeled product until supplies are gone and then will sell Alvogen labeled product.

- Sandoz had clindamycin injection on shortage due to increased demand.
- Sagent has clindamycin injection on shortage due to manufacturing delays.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1029#sthash.cIHembUa.dpuf>

### **Cisatracurium Besylate Injection**

**April 14, 2016**

#### **Reason of the Shortage**

- Fresenius Kabi has cisatracurium besylate injection on shortage due to increased demand.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1234#sthash.85LxVWVl.dpuf>

### **Yellow Fever Vaccine Injection**

**April 18, 2016**

#### **Reason of the Shortage**

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

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=383#sthash.CL6jA4uE.dpuf>

### **Tamsulosin Hydrochloride Capsules**

**April 18, 2016**

#### **Reason of the Shortage**

- Boehringer Ingelheim had tamsulosin capsules on shortage due to production delays.
- Actavis and Zydus state the reason for the shortage was increased demand.
- Aurobindo is not marketing the 100 count size.
- Caraco cannot provide a reason for the shortage.
- Teva discontinued tamsulosin 0.4 mg capsules in April 2014.
- Par discontinued tamsulosin 0.4 mg capsules.
- Sandoz has tamsulosin on shortage due to increased demand for the product.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1112#sthash.b718Pp3O.dpuf>

### **Methylphenidate Transdermal**

**April 18, 2016**

#### **Reason of the Shortage**

- Noven has Daytrana patches on shortage due to shipping delays

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1216#sthash.ZmTGM1Ze.dpuf>

### Indigo Carmine Injection

April 18, 2016

#### Reason of the Shortage

- American Regent has indigo carmine on back order due to manufacturing delays.
- Akorn has discontinued production of indigo carmine due to shortage of raw material.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=861#sthash.U4FZPoyA.dpuf>

### Hydroxyamphetamine Hydrobromide and Tropicamide Ophthalmic Solution

April 18, 2016

#### Reason of the Shortage

- Akorn has Paremyd on shortage due to manufacturing delays.
- No clinical trial data were found to support the use of Paremyd in the diagnosis of Horner Syndrome

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1193#sthash.tchPbsqx.dpuf>

### Fomepizole Injection

April 18, 2016

#### Reason of the Shortage

- Sandoz could not provide a reason for the shortage. However, fomepizole injection is manufactured by Emcure for Sandoz. An Emcure manufacturing site was recently noted to have FDA observations related to GMP and aseptic practices.
- X-Gen has fomepizole injection available.
- Mylan Institutional has fomepizole injection available.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1173#sthash.7JI8vOaG.dpuf>

### Cefpodoxime

April 18, 2016

#### Reason of the Shortage

- Aurobindo could not provide a reason for the shortage.
- Pfizer has discontinued Vantin.
- Ranbaxy has an import ban on all solid medications including cefpodoxime.
- Sandoz could not provide a reason for the shortage.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=793#sthash.ndWxKYH9.dpuf>

### Diltiazem Injection

April 19, 2016

#### Reason of the Shortage

- Akorn states the reason for the shortage is increased demand due to market conditions.
- Hospira states the reasons for the shortage are manufacturing delays and increases in demand.

- West-Ward had diltiazem injection on shortage due to manufacturing delays caused by increased demand due to current market conditions

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=217#sthash.EWE9asPZ.dpuf>

### **Hydralazine Injections**

**April 20, 2016**

#### **Reason of the 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.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1129#sthash.OQj9mk1R.dpuf>

### **Sodium Acetate Injection**

**April 25, 2016**

#### **Reason of the Shortage**

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

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=762#sthash.Mp3wMlX.dpuf>

### **Propranolol Injection**

**April 25, 2016**

#### **Reason of the Shortage**

- Ben Venue closed its plant in Bedford, Ohio in July 2014.
- Fresenius Kabi had propranolol injection on back order due to shortage of raw materials.
- Sandoz cannot provide a reason for the shortage.
- West-Ward has propranolol injection available.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1091#sthash.ZZpGEUJE.dpuf>

### **Ofloxacin Ophthalmic Solution**

**April 25, 2016**

#### **Reason of the Shortage**

- Allergan has Ocuflax ophthalmic solution available.
- Akorn did not provide a reason for the shortage.
- Rising did not provide a reason for the shortage.
- Valeant did not provide a reason for the shortage.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1235#sthash.Q5mKEISu.dpuf>

### Morphine PCA Vials

April 25, 2016

#### Reason of the Shortage

- Hospira has morphine PCA vials on shortage due to quality assurance issues.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1220#sthash.D3chkTmF.dpuf>

### Flumazenil Injection

April 25, 2016

#### Reason of the 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.

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

### Chlorpromazine Injection

April 25, 2016

#### Reason of the Shortage

- West-Ward has chlorpromazine injection on shortage due to manufacturing delays.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1188#sthash.bfvNAZvM.dpuf>

### Cefotetan Disodium Injection

April 25, 2016

#### Reason of the Shortage

- BBraun had cefotetan on allocation due to current market conditions.
- Fresenius Kabi states the reason for the shortage is manufacturing delay.
- Teligent received FDA approval for Cefotan in 2015. Teligent launched Cefotan in March 2016.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1097#sthash.lIz6oISA.dpuf>

### Caffeine and Sodium Benzoate Injection

April 25, 2016

#### Reason of the Shortage

- American Regent cannot provide a reason for the shortage of caffeine and sodium benzoate injection.
- American Regent is the sole manufacturer of caffeine and sodium benzoate injection.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=817#sthash.egn7yTyO.dpuf>



## Atropine Sulfate Ophthalmic Solution

April 25, 2016

### Reason of the Shortage

- Alcon has discontinued Isopto Atropine.
- Akorn received FDA approval for atropine sulfate 1% ophthalmic solution in July 2014; this new product launched in January 2015.
- Sandoz has discontinued atropine sulfate ophthalmic solution.
- Valeant discontinued their atropine sulfate 1% ophthalmic solution products in 2015.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1146#sthash.EtCU7YTq.dpuf>

## Vitamin E Aqueous Oral Solution

April 26, 2016

### Reason of the 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.

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

## Poliovirus Vaccine Inactivated

April 26, 2016

### Reason of the Shortage

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

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

## Liotrix Tablets

April 26, 2016

### Reason of the Shortage

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

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=24#sthash.8fgFWIbZ.dpuf>

## Haemophilus B Conjugate Vaccine

April 26, 2016

### Reason of the Shortage

- GlaxoSmithKline has Hiberix available.
- 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.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1052#sthash.HWaOW57A.dpuf>

### **Gadoteridol Injection**

**April 26, 2016**

#### **Reason of the Shortage**

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

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

### **Ethiodized Oil**

**April 26, 2016**

#### **Reason of the 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.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=618#sthash.tdDtsgD3.dpuf>

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

**April 26, 2016**

#### **Reason of the Shortage**

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

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=922#sthash.vnUA7oPn.dpuf>

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

**April 26, 2016**

#### **Reason of the Shortage**

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

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=921#sthash.GD0ViGWY.dpuf>

### **Amikacin Injection**

**April 26, 2016**

#### **Reason of the Shortage**

- West-Ward launched amikacin injection in 2 mL and 4 mL vials in December 2015.
- Teva's product is unavailable due to manufacturing delays.
- 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

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=501#sthash.nbGFPugf.dpuf>

### Sodium Phosphate Injection

April 27, 2016

#### Reason of the Shortage

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

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=770#sthash.L5Y8HLz1.dpuf>

### Potassium Acetate Injection

April 27, 2016

#### Reason of the Shortage

- American Regent has potassium acetate on shortage due to manufacturing delays.
- Hospira has 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.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=668#sthash.WDJPJ6y5.dpuf>

### Metoprolol Injection

April 27, 2016

#### Reason of the Shortage

- American Regent has metoprolol injection on shortage due to manufacturing delays.
- Ben Venue stopped production in its plant in Bedford, Ohio and closed in July 2014.
- Claris has metoprolol injection on allocation.
- Fresenius Kabi states the shortage was due to increased demand for the product.
- Hospira has metoprolol injection available.
- Novartis discontinued Lopressor injection in mid-2015.
- Sagent states the shortage is due to increased demand for the product.
- Sandoz discontinued metoprolol injection in 2015.
- West-Ward had metoprolol injection on shortage due to increased demand.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=813#sthash.3XxslJIT.dpuf>

### Bleomycin Sulfate Injection

April 27, 2016

#### Reason of the 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.

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

## Sodium Bicarbonate Injection

April 28, 2016

### Reason of the Shortage

- Amphastar has sodium bicarbonate on shortage due to increased demand and has a new NDC number for the product.
- Fresenius Kabi is not currently manufacturing sodium bicarbonate 4.2% 5 mL vials.
- Hospira has sodium bicarbonate on shortage due to manufacturing delays.
- Hospira is the sole supplier of the 4.2% 10 mL syringes used in pediatric patients.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=788#sthash.y04IXvL0.dpuf>

## Doxycycline Hyclate Injection

April 28, 2016

### Reason of the Shortage

- Fresenius Kabi cannot provide a reason for the doxycycline injection shortage.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=431#sthash.mmK7c2LP.dpuf>

## Desmopressin Injection

April 28, 2016

### Reason of the Shortage

- Teva and Hospira have desmopressin injection on shortage due to manufacturing delays.
- Ferring divested generic desmopressin to Amring Pharmaceuticals in January 2016.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1010#sthash.wBgSVQcU.dpuf>

## Ofloxacin Otic Solution

April 29, 2016

### Reason of the Shortage

- Apotex discontinued ofloxacin otic solution in early-2015.
- Sandoz discontinued ofloxacin otic solution in mid-2015.
- Valeant cannot provide a reason for the shortage.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1187#sthash.904aEeoq.dpuf>

## Neomycin and Polymyxin B Sulfates and Dexamethasone Ophthalmic Ointment

April 29, 2016

### Reason of the Shortage

- Perrigo has neomycin and polymyxin B sulfates and dexamethasone ophthalmic ointment on shortage due to manufacturing issues.
- Sandoz has neomycin and polymyxin B sulfates and dexamethasone ophthalmic ointment on shortage due to increased demand.

- Valeant has neomycin and polymyxin B sulfates and dexamethasone ophthalmic ointment on shortage due to manufacturing delay.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1225#sthash.xlXiC7zQ.dpuf>

### **Ketorolac Tromethamine Injection**

**April 29, 2016**

#### **Reason of the Shortage**

- BD Rx has ketorolac injection available. BD RX is now part of Fresenius Kabi.
- Fresenius Kabi has ketorolac injection available.
- Hospira has ketorolac on shortage due to manufacturing delays for quality improvement activities and increased demand for the product.
- Sagent states the reason for the shortage is demand exceeding supply.
- 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.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=593#sthash.Xn1hJgX.dpuf>

### **Doxorubicin Injection**

**April 29, 2016**

#### **Reason of the Shortage**

- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired Adriamycin injection from Bedford in July 2014. West-Ward is not actively marketing Adriamycin injection at this time.
- Teva has doxorubicin solution for injection on allocation due to current market conditions.
- Fresenius Kabi has doxorubicin solution for injection available.
- Caraco has discontinued doxorubicin solution for injection 25 mL and 100 mL vials.
- Pfizer had doxorubicin solution for injection on shortage due to shipping delays.
- Sagent has doxorubicin solution for injection on back order due to manufacturing delays.
- Mylan cannot provide a reason for the reason for the doxorubicin solution for injection available.
- Actavis has doxorubicin injection available.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=464#sthash.CS4W9oN5.dpuf>

### **Tromethamine Injection**

**May 02, 2016**

#### **Reason of the Shortage**

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

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=687#sthash.gsMeQQL0.dpuf>

### **Tigecycline Injection**

**May 02, 2016**

#### **Reason of the Shortage**

- Pfizer has Tygacil on shortage due to manufacturing delays.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1218#sthash.5rEwNNYG.dpuf>

### **Prochlorperazine Edisylate Injection**

**May 02, 2016**

#### **Reason of the Shortage**

- Heritage Pharmaceuticals states the reason for the shortage was manufacturing delay.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1063#sthash.0XzGAZ3b.dpuf>

### **Phenytoin Injection**

**May 2, 2016**

#### **Reason of the Shortage**

- Hospira has phenytoin sodium injection on shortage due to manufacturing delay.
- X-Gen is no longer marketing phenytoin sodium injection.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=740#sthash.wJsMxU3C.dpuf>

### **Methylprednisolone Sodium Succinate Injection**

**May 2, 2016**

#### **Reason of the Shortage**

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

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1077#sthash.0N62wWnl.dpuf>

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

**May 2, 2016**

#### **Reason of the 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.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=932#sthash.wNB5EgNY.dpuf>

## Zolpidem Tartrate Immediate Release Tablets

May 3, 2016

### Reason of the Shortage

- Aurobindo could not provide a reason for the shortage.
- Major discontinued zolpidem tartrate immediate release tablets.
- Mylan has zolpidem available.
- Torrent has zolpidem available.

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

## Promethazine Injection

May 3, 2016

### Reason of the Shortage

- Teva states the shortage is due to manufacturing delays.
- West-Ward states the shortage was due to manufacturing delays.
- Hospira states the shortage is due to manufacturing delays.
- X-Gen is in the process of changing NDC numbers for promethazine injection and awaiting FDA approval for two new presentations.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=654#sthash.3oZNGyel.dpuf>

## Lorazepam injectable presentations

May 3, 2016

### Reason of the Shortage

- Bedford discontinued lorazepam injection in May, 2011.
- West-Ward has product on shortage due to manufacturing delays.
- Hospira has product on shortage due to manufacturing delays.
- Akorn has not provided a reason for the shortage.
- Amphastar has product available

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=747#sthash.sX6kd8yA.dpuf>

## Levetiracetam Injection

May 3, 2016

### Reason of the Shortage

- American Regent states the reason for the shortage is manufacturing delay.
- AuroMedics has product available.
- Caraco has temporarily discontinued levetiracetam. Hospira has product available.
- Sagent has product available.
- X-Gen states the reason for the shortage is change in manufacturing site.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1183#sthash.s06CFHOr.dpuf>

## Leucovorin Calcium Injection

May 3, 2016

### Reason of the Shortage

- Fresenius Kabi has leucovorin on shortage due to increase demand.
- Teva had 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.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=488#sthash.pxRYGX8g.dpuf>

## L-Cysteine Hydrochloride Injection

May 3, 2016

### Reason of the Shortage

- American Regent has L-cysteine hydrochloride injection on back order due to manufacturing delays.
- Sandoz has L-cysteine hydrochloride injection available.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=632#sthash.yw6xQKff.dpuf>

## Gentamicin injection

May 3, 2016

### Reason of the Shortage

- Hospira has discontinued all premixed bags except for the 60 mg/50 mL size. This presentation is on long-term back order due to manufacturing delays.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=728#sthash.PKvw4ZLV.dpuf>

## Cyclopentolate Hydrochloride and Phenylephrine Hydrochloride Ophthalmic Solution

May 3, 2016

### Reason of the Shortage

- Alcon has Cyclomydril ophthalmic solution on back order due to production delays.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1214#sthash.tLeiQNwk.dpuf>

## Potassium Chloride Injection

May 4, 2016

### Reason of the 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.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=696#sthash.6CWMUfp9.dpuf>



### Imipenem Cilastatin Injection

May 4, 2016

#### Reason of the Shortage

- Fresenius Kabi has imipenem and cilastatin sodium injection on shortage due to increased demand. .
- Hospira has imipenem and cilastatin sodium injection on shortage due to manufacturing delays.
- Merck has Primaxin vials on shortage due to increased demand.
- Merck has discontinued Primaxin ADD-Vantage vials.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1182#sthash.AWL3ux7D.dpuf>

### Haloperidol Decanoate Injection

May 4, 2016

#### Reason of the Shortage

- Teva products are on shortage due to manufacturing delays.
- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired haloperidol decanoate injection from Bedford in July 2014. West-Ward is not actively marketing haloperidol decanoate injection at this time.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=526#sthash.Y4siyLqP.dpuf>

### 23.4% Sodium Chloride Concentrated Solution for Injection

May 4, 2016

#### Reason of the Shortage

- Fresenius Kabi has 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.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1194#sthash.fkTOp4EL.dpuf>

### Penicillin G Procaine Injection

May 5, 2016

#### Reason of the Shortage

- Pfizer has penicillin G procaine on shortage due to manufacturing delays.
- Pfizer is the sole supplier of penicillin G procaine.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1238#sthash.Wgl8TuVR.dpuf>

### Penicillin G Benzathine

May 5, 2016

#### Reason of the Shortage

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

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1232#sthash.xg6QzFYu.dpuf>

### Electrolyte Concentrate

May 5, 2016

#### Reason of the Shortage

- American Regent has Nutrilyte and Nutrilyte II on back order due to manufacturing delays.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1054#sthash.Lg3mBY16.dpuf>

### Dextrose (25%) Injection

May 5, 2016

#### Reason of the Shortage

- Hospira has 25% dextrose syringes on shortage due to increased demand.
- Hospira is the sole supplier of 25% dextrose syringes.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1011#sthash.q5dRw3eG.dpuf>

### Cefotaxime Injection

May 5, 2016

#### Reason of the Shortage

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

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=826#sthash.u9n9NDHu.dpuf>

### Atropine Sulfate Injection

May 5, 2016

#### Reason of the Shortage

- Amphastar had atropine on shortage due to increased demand.
- Hospira states the shortage was due to manufacturing delays.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=814#sthash.dV8aXqDw.dpuf>

### Vecuronium Bromide Injection

May 9, 2016

#### Reason of the Shortage

- Hospira has vecuronium available
- Teva states the shortage is due to manufacturing delays.
- Pfizer sold vecuronium injection to Mylan Institutional in December 2013.
- Ben Venue has stopped production in its plant in Bedford, Ohio and closed in 2014.
- Caraco has vecuronium injection available. NDCs changed in mid-2015.
- Sagent temporarily suspended the manufacture of vecuronium 10 mg and 20 mg vials.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=490#sthash.msT08Rli.dpuf>

### Torsemid Injection

May 9, 2016

#### Reason of the Shortage

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

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=344#sthash.ELoICKOc.dpuf>

### Synthetic Conjugated Estrogen

May 9, 2016

#### Reason of the Shortage

- Teva discontinued Cenestin in late-August 2014.
- Premarin is not affected by this shortage.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1087#sthash.EajRrcyM.dpuf>

### Sufentanil Injection

May 9, 2016

#### Reason of the Shortage

- West-Ward has sufentanil on shortage due to manufacturing delays.
- Hospira has sufentanil on shortage due to manufacturing delays.
- Akorn could not provide a reason for the shortage.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=823#sthash.hgvH5qCf.dpuf>

### Propranolol Hydrochloride Tablets

May 9, 2016

#### Reason of the Shortage

- Actavis has propranolol tablets available.
- Heritage is not marketing propranolol tablets at this time.
- Northstar discontinued all propranolol tablets in February 2015.
- Mylan Institutional discontinued propranolol unit-dose tablets. The 10 mg tablets were discontinued in March 2013, the 20 mg tablets were discontinued in May 2014, and the 40 mg tablets were discontinued in January 2015.
- Qualitest refuses to provide product availability as the company considers it proprietary information.
- Teva could not provide a reason for the shortage.
- Major discontinued propranolol tablets in early 2016.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1189#sthash.AOkN9miJ.dpuf>

## Indomethacin Capsules

May 9, 2016

### Reason of the Shortage

- Mylan, Glenmark, and Teva did not provide a reason for the shortage.

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

## Haloperidol Lactate Injection

May 9, 2016

### Reason of the Shortage

- Patriot Pharmaceuticals has haloperidol lactate available.
- Sagent has haloperidol lactate on shortage due to manufacturing delays.
- Teva has haloperidol lactate on shortage due to manufacturing delays.
- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired several products from Bedford Laboratories in July 2014 including haloperidol lactate injection. West-Ward is not actively marketing haloperidol lactate at this time.
- Janssen has Haldol injection available.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=527#sthash.qG1zTiUP.dpuf>

## Ampicillin Injection

May 9, 2016

### Reason of the Shortage

- Fresenius Kabi states the reason for the shortage is increased demand.
- Sagent states the reason for the shortage is manufacturing delay.
- Sandoz cannot provide a reason for the shortage. WG Critical Care states the reason for the shortage was increased demand.
- WG Critical Care discontinued ampicillin 250 mg vials in early 2016.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1226#sthash.oxyWPNs6.dpuf>

## Tropicamide 1% Ophthalmic Solution

May 10, 2016

### Reason of the Shortage

- Akorn has tropicamide 1% ophthalmic solution available.
- Sandoz cannot provide a reason for the shortage of tropicamide 1% ophthalmic solution.
- Valeant has tropicamide 1% ophthalmic solution available.

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1215>

## Morphine Injections

May 10, 2016

### Reason of the 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.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=664#sthash.j7ImHPYt.dpuf>

## Epinephrine Injection

May 10, 2016

### Reason of the Shortage

- American Regent discontinued both epinephrine presentations in early 2015.
- Amphastar states the shortage is due to increased demand.
- BPI Labs received FDA approval for epinephrine injection in 2014 and the company launched product in February 2015.
- Hospira has epinephrine syringes on shortage due to manufacturing delays.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=685#sthash.mt5U5zOe.dpuf>

## Cardioplegic Solution for Cardiac Perfusion

May 10, 2016

### Reason of the Shortage

- Baxter states they are experiencing an increased demand.
- Hospira states the reason for the shortage was manufacturing delay.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1172#sthash.odnU9YK8.dpuf>

## Calcitriol Injection

May 10, 2016

### Reason of the Shortage

- Akorn cannot provide a reason for the shortage.
- American Regent has had calcitriol injection unavailable since 2011.
- Calcitriol capsule and oral solution presentations are available from multiple manufacturers.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=940#sthash.kDc3HX1v.dpuf>

## Bupivacaine Injection

May 10, 2016

### Reason of the 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.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=864#sthash.H4CSIOwW.dpuf>

### BCG Vaccine Live Intravesical

May 10, 2016

#### Reason of the 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 –

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=915#sthash.zYnQ8bv6.dpuf>

### Oxytocin Injection

May 11, 2016

#### Reason of the 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.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=876#sthash.aZ8mjaGg.dpuf>

### Chloramphenicol Sodium Succinate Injection

May 11, 2016

#### Reason of the Shortage

- Fresenius Kabi had chloramphenicol injection on back order due to a raw material shortage.
- Fresenius Kabi is the sole supplier of chloramphenicol injection.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1068#sthash.CN6ZUMO6.dpuf>

### Tobramycin Injection

May 12, 2016

#### Reason of the Shortage

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

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

## Sumatriptan Nasal Spray

May 12, 2016

### Reason of the Shortage

- GlaxoSmithKline could not provide a reason for the shortage.
- Sandoz has sumatriptan nasal spray on shortage due to product constraints.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1222#sthash.qBdsDUTG.dpuf>

## Piperacillin Tazobactam Injection

May 12, 2016

### Reason of the 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.
- Sagent has piperacillin/tazobactam on shortage due to increased demand.
- Pfizer has Zosyn on shortage due to manufacturing delays. Pfizer estimates there will be supply shortages through December 2015 for the single dose vials and 1st quarter 2017 for the bulk vials.
- Sandoz discontinued piperacillin/tazobactam in late 2015.
- WG Critical Care states the reason for the shortage is increased demand.

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

## Olanzapine Injection

May 12, 2016

### Reason of the Shortage

- American Regent cannot provide a reason for the shortage.
- Sandoz has olanzapine injection on shortage due to increase demand.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1093#sthash.INTKCPtR.dpuf>

## Morrhuate Sodium Injection

May 12, 2016

### Reason of the Shortage

- American Regent has morrhuate sodium injection on shortage due to manufacturing delays.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=903#sthash.PIB4QesA.dpuf>

## Lactated Ringer's Injection Bags

May 12, 2016

### Reason of the Shortage

- Baxter is experiencing increased demand.
- BBraun has lactated ringer's available for current customers.

- Hospira has lactated ringer's on shortage due to increased demand.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1078#sthash.amKZ5JzY.dpuf>

### Famotidine Injection

May 12, 2016

#### Reason of the Shortage

- Ben Venue stopped production in its plant in Bedford, Ohio and closed in July 2014.
- West-Ward states the shortage was due to manufacturing delays.
- Oral famotidine products are not affected by this shortage.
- Pfizer launched famotidine injections in March, 2012.
- Mylan Institutional acquired famotidine injections from Pfizer on December 6, 2013.
- Baxter has famotidine premixed bags available.
- Fresenius Kabi has famotidine injection available.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=810#sthash.dOk5Q58Q.dpuf>

### Dexamethasone Sodium Phosphate

May 12, 2016

#### Reason of the Shortage

- American Regent has dexamethasone sodium phosphate on shortage due to manufacturing delays.
- AuroMedics has dexamethasone sodium phosphate is available.
- Fresenius Kabi has dexamethasone sodium phosphate is available.
- West-Ward has dexamethasone sodium phosphate is available.
- Mylan Institutional states the shortage is due to increased demand.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=751#sthash.Jjfo8x95.dpuf>

### Carboplatin Solution for Injection

May 12, 2016

#### Reason of the 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.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1005#sthash.UJ6So6ec.dpuf>



## Calcium Gluconate Injection

May 12, 2016

### Reason of the 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.

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

## Ammonium Chloride Injection

May 12, 2016

### Reason of the Shortage

- Hospira states the shortage of ammonium chloride is due to manufacturing delays.
- Hospira is the sole manufacturer of ammonium chloride injection.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=933#sthash.9iROPsy.dpuf>

## Theophylline Extended-Release Tablets

May 13, 2016

### Reason of the Shortage

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

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1221#sthash.7Q5pHWmb.dpuf>

## Retepase Injection

May 13, 2016

### Reason of the Shortage

- Chiesi USA acquired Cornerstone Therapeutics in March 2014.
- Cornerstone Therapeutics acquired EKR Therapeutics in June 2012. EKR Therapeutics had previously purchased Retavase from PDL BioPharma.
- Cornerstone Therapeutics was seeking FDA approval of a new supplier of the active pharmaceutical ingredient for Retevase.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=569#sthash.16eEkiCR.dpuf>

## Phenazopyridine Hydrochloride

May 13, 2016

### Reason of the Shortage

- Amneal Pharmaceuticals, Avkare, SDA Laboratories discontinued phenazopyridine tablets.
- Gemini Laboratories has new NDC numbers for Pyridium products. Gemini has product available.
- Marlex could not provide a reason for the shortage.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1144#sthash.WkwMTBYS.dpuf>

### **Furosemide Injection**

**May 13, 2016**

#### **Reason of the Shortage**

- Fresenius Kabi has furosemide injection available.
- American Regent has furosemide injection on shortage due to manufacturing delays.
- Hospira has furosemide injection available.
- Wockhardt has discontinued all furosemide injection presentations.
- Claris has furosemide injection available.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=636#sthash.PJEqqql.dpuf>

### **Ceftriaxone Sodium Injection**

**May 13, 2016**

#### **Reason of Shortage**

- Fresenius Kabi states the reason for the shortage is increased demand.
- Hospira states the reason for the shortage was manufacturing delay. S
- agent states the reason for the shortage is increased demand.
- Sandoz cannot provide a reason for the shortage.
- WG Critical Care states the reason for the shortage is increased demand.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1101#sthash.NU6mBXYb.dpuf>

### **Methylprednisolone Acetate Injection**

**May 16, 2016**

#### **Reason of Shortage**

- Sandoz and Teva could not provide a reason for the shortage.
- Pfizer has Depo-Medrol injection on a short-term shortage due to increased demand of Solu-Medrol.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=923#sthash.XUJEr5Gx.dpuf>

### **Lidocaine Injection**

**May 16, 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. –

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=859#sthash.JYOATeys.dpuf>

## Fluorouracil Injection

May 16, 2016

### Reason of Shortage

- Accord cannot provide a reason for the shortage.
- Fresenius Kabi states the reason for the shortage is increased demand.
- Teva states the reason for the shortage is increased demand.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=798#sthash.AmaCRHTD.dpuf>

## Eptifibatide Injection

May 16, 2016

### Reason of Shortage

- Merck states the reason for the shortage is manufacturing delay.
- AuroMedics launched eptifibatide injection in December 2015.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1210#sthash.VHZmChxo.dpuf>

## Dextrose (50%) Injection

May 16, 2016

### Reason of Shortage

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

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1012#sthash.3J33aZvb.dpuf>

## Cefepime Injection

May 16, 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.

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

## Calcium Chloride Injection

May 16, 2016

### Reason of Shortage

- American Regent has calcium chloride on shortage due to manufacturing delays.

- Amphastar had calcium chloride on shortage due to increased demand.
- Hospira has calcium chloride on shortage due to manufacturing delay.
- Mylan Institutional has withdrawn calcium chloride syringes from the market. The company recalled the syringes in April 2015 due to incompatibility of the syringes and some needless adaptors.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=941#sthash.kGbuH5Xo.dpuf>

## **Ampicillin Sulbactam**

**May 16, 2016**

### **Reason of Shortage**

- Hospira states that ampicillin sulbactam vials are on back order due to manufacturing delay.
- 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.
- Pfizer and Sandoz cannot provide a reason for the shortage.
- Mylan Institutional discontinued ampicillin sulbactam 1.5 gram and 3 gram vials.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=805#sthash.fBtabDu0.dpuf>

\*Please refer to ASHP website for more information

## NEW DRUGS COMING TO MARKET

PRODUCT	MFR	ROUTE	INDICATION	PHARMACOLOGY	MARKET RELEASE
Obeticholic acid	Intercept	Oral	Primary biliary cirrhosis	Farnesoid-X receptor agoinst	5/29/2016
Rociletinib (CO-1686)	Clovis Oncology	Oral	Mutant EGFR T790M NSCLC	Irreversible inhibitor of EGFR	6/28/2016
Zinbryta (daclizumab HYP)	Biogen	Subcutaneous	Multiple sclerosis	Interleukin-2R receptor inhibitor	Q2 2016
Sarilumab	Regeneron/ Sanofi	Subcutaneous	RA	Targets interleukin-6r	10/30/2016
Translarna™ (Ataluren)	PTC Therapeutics	Oral	Nonsense mutation Duchenne Muscular Dystrophy and Cystic Fibrosis	Gene transcription modulate, protein restoration	Q4 2016
Brodalumab	Valeant	Subcutaneous	Psoriasis	Interleukin-17 inhibitor	Q4 2016
Andexanet	Pfizer	IV	Anticoagulant reversal	Factor Xa antidote	Q4 2016
Baricitinib	Eli-Lilly	Oral	RA	Janus Kinase-1 and 2 inhibitor	2016
Daclatasvir/Asuna previr/Beclabuvir	Bristol Myers Squibb	Oral	HCV genotype 1	NS5B polymerase inhibitor/ NS5A inhibitor/ protease inhibitor	2016
Buparlisib	Novartis	Oral	2 <sup>nd</sup> line for metastatic, ER+ breast cancer resistant to aromitase inhibitors	Pan-class 1 P13K inhibitor	2016
Ztilido (lidocaine patch 1.8%)	Scilex	Topical patch	Post-herpetic neuralgia	Local anesthetic	2016
Lupuzor™ (rigerimod)	ImmunPharm a PLC	Subcutaneous	Systemic lupus erythematosus	P140 peptide	2016
Elagolix	Abbvie	Oral	Uterine fibroids and endometiosis	GnRH antagonist	2016
Midostaurin (PKC412)	Novartis	Oral	AML	Kinase inhibitor	2016
Amigal (Migalastat)	Amicus	Oral	Fabry disease	Binds alpha-Gal A	2016

PRODUCT	MFR	ROUTE	INDICATION	PHARMACOLOGY	MARKET RELEASE
Baxdela (delafloxacin)	Melinta	Oral and IV	Gonorrhea and bacterial skin/soft tissue infections	Fluoroquinolone	2016
Glycopyrronium/formoterol (PT-003)	AstraZeneca	Inhaler	Asthma/COPD	Anticholinergic combination	2016
Eravacycline	Tetraphase	Oral and IV	Complicated UTIs	Noval synthetic tetracycline	2016
MK-8342B	Merck	Vaginal ring	Contraception	Contraceptive	2016
Hydrocodone ER (CEP-33237)	Teva	Oral	Pain	Opioid receptor agonist	2016
Oxycodone/naltrexone ER (ALO-02)	Pfizer	Oral	Pain	Opioid receptor agonist	2016
Ribociclib	Novartis	Oral	HR+, HER2-, postmenopausal advanced breast cancer	CDK4/6 inhibitor	2016
Pacritinib	CTI BioPharma	Oral	Myelofibrosis	Janus Kinase-2/ FMS-like tyrosine kinase-3 inhibitor	2016
Surotomycin	Cubist	Oral	C. diff associated diarrhea	Antibacterial lipopeptide	2016
Guselkumab	Janssen	Subcutaneous	Psoriasis	IL-23 Inhibitor	2017
Brigatinib	Ariad	Oral	ALK + Advanced NSCLC	ALK Inhibitor	2017
ABT-530/ABT-493	AbbVie	Oral	NS5A Inhibitor/Protease Inhibitor	Hepatitis C Genotypes 1-6	2017
COBI/dRV/FTC/TAF	Janssen	Oral	Booster/Protease inhibitor/NRTI/NRTI	HIV	2017
PRO-140	CytoDyne	Subcutaneous	Viral Entry Inhibitor	HIV	2017
Benralizumab	AstraZeneca	Subcutaneous	Interleukin-5 Inhibitor	Uncontrolled Asthma	2017