



**June 2015\***

Drug Information Update

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## NEW GENERICS TO MARKET

GENERIC DRUG NAME	STRENGTH & DOSAGE FORM	GENERIC MANUFACTURER	BRAND NAME	APPROVAL DATE
TOLCAPONE	100 MG, TABLET	PAR PHARMA	TASMAR	05/08/15
NORETHINDRONE AC-ETH ESTRADIOL	0.5 MG-2.5 MCG, TABLET	GLENMARK PHARMA	FEMHRT	05/11/15
LIDOCAINE/TETRACAINE	7% -7%, CREAM (G)	BELCHER PHARMAC	PLIAGLIS	05/13/15
BUTALB/ACETAMINOPHEN/CAFFEINE	50-325/15, SOLUTION	GM PHARM	DOLGIQ LQ	05/15/15
RISEDRONATE SODIUM	35 MG, TABLET DR	TEVA ; ACTAVIS PHARMA	ATELVIA	05/19/15 ; 5/29/15
ALOSETRON HCL	0.5 MG, TABLET	ROXANE ; ACTAVIS PHARM	LOTRONEX	05/22/15 ; 05/26/15
ALOSETRON HCL	1 MG, TABLET	ROXANE ; ACTAVIS	LOTRONEX	05/22/15 ; 05/26/15
HYDROCORTISONE/IODOQUINOL/A LOE	1.9% - 1%, CREAM PACK	BOWTN LABS, LLC	VYTONE	06/02/15
NAFTIFINE HCL	1%, CREAM (G)	RENAISSANCE PHARM	NAFTIN	06/02/15
RISEDRONATE SODIUM	35 MG, TABLET	TEVA ; ACTAVIS PHARMA	ACTONEL	06/02/15
RISEDRONATE SODIUM	30 MG, TABLET	TEVA ; ACTAVIS PHARMA	ACTONEL	06/02/15
RISEDRONATE SODIUM	5 MG, TABLET	TEVA ; ACTAVIS PHARMA	ACTONEL	06/02/15
SILDENAFIL CITRATE	10 MG/12.5 ML, VIAL	AUROMEDICS PHAR	REVATIO	06/02/15
PNV73/IRON,CARB&GLU/FA/DSS/D HA	35 MG IRON-1 MG-50 MG-300 MG, COMBO PACK	METHOD PHARMACE	CITRANATAL ASSURE	06/04/15
TRAMADOL HCL	100 MG, CPBP 25-75	TRIGEN LABORATORY	CONZIP	06/05/15
TRAMADOL HCL	200 MG, CPBP 25-75	TRIGEN LABORATORY	CONZIP	06/05/15
TRAMADOL HCL	300 MG, CPBP 25-75	TRIGEN LABORATORY	CONZIP	06/05/15
SALICYLIC ACID	28.50%, SOL-FILMER	KMM PHARMACEUTICAL	ULTRASAL-ER	06/05/15
DULOXETINE HCL	40 MG, CAPSULE DR	LUPIN PHARMACEUTICAL	IRENKA	06/08/15
PNV72/IRON,CARB&GLU/FA/DSS/D HA	90 MG IRON-1 MG-50 MG-300 MG	METHOD PHARMACE	CITRANATAL 90 DHA	06/09/15

## NEW DRUG ENTITIES

DESCRIPTION	BRAND NAME	GENERIC NAME	STRENGTH	NOTES
PRENATAL VITAMIN PREPARATIONS	ENBRACE HR	PRENATAL #92/IRON/FA #8/PS-DHA	1.5-8.73MG	NEW COMBINATION
ANALGESICS, NARCOTICS	MORPHINE SULFATE-0.9% NACL	MORPHINE SULFATE/0.9% NACL/PF	5 MG/ML	NEW STRENGTH
ANTIHYPERLIPIDEMIC - MTP INHIBITOR	JUXTAPID	LOMITAPIDE MESYLATE	40 MG	NEW STRENGTH
ANTIHYPERLIPIDEMIC - MTP INHIBITOR	JUXTAPID	LOMITAPIDE MESYLATE	60 MG	NEW STRENGTH
ANTIHYPERLIPIDEMIC - MTP INHIBITOR	JUXTAPID	LOMITAPIDE MESYLATE	30 MG	NEW STRENGTH
DIAGNOSTIC PREPARATIONS, MISCELLANEOUS	GLUCAGON HCL	GLUCAGON HCL	1 MG	NEW FORMULATION
ANDROGENIC AGENTS	TESTONE CIK	TESTOSTERONE CYPIONATE	200 MG/ML	NEW DOSAGE FORM
ANALGESICS, NARCOTICS	IONSYS	FENTANYL HCL	40 MCG	NEW STRENGTH AND DOSAGE FORM
BETA-ADRENERGIC AND ANTICHOLINERGIC COMBINATIONS	STIOLTO RESPIMAT	TIOTROPIUM BR/OLODATEROL HCL	2.5-2.5MCG	NEW COMBINATION
KERATOLYTICS	UREVAZ	UREA	44 %	NEW ENTITY
FACTOR IX PREPARATIONS	IXINITY	FACTOR IX HUMAN RECOMB, THR 148	500 UNIT	NEW ENTITY
FACTOR IX PREPARATIONS	IXINITY	FACTOR IX HUMAN RECOMB, THR 148	1000 UNIT	NEW ENTITY
FACTOR IX PREPARATIONS	IXINITY	FACTOR IX HUMAN RECOMB, THR 148	1500 UNIT	NEW ENTITY
CEPHALOSPORINS - 1ST GENERATION	CEFAZOLIN-0.9% NACL	CEFAZOLIN SODIUM IN 0.9 % NACL	3 G/100 ML	NEW STRENGTH AND DOSAGE FORM
ANTISERA	VARIZIG	VARICELLA-ZOSTER IG/MALTOSE	125/1.2 ML	NEW VACCINE
NARCOTIC ANTITUSSIVE- 1ST GENERATION ANTIHISTAMINE	PROMETHAZINE-CODEINE	PROMETHAZINE HCL/CODEINE	6.25-10/5	5 ML IN 1 CUP
SEROTONIN-NOREPINEPHRINE REUPTAKE-INHIB (SNRIS)	IRENKA	DULOXETINE HCL	40 MG	NEW STRENGTH
ANTI PSYCHOTICS, ATYPICAL, DOPAMINE, & SEROTONIN ANTAG	INVEGA TRINZA	PALIPERIDONE PALMITATE	273MG/.875	NEW FORMULATION

DESCRIPTION	BRAND NAME	GENERIC NAME	STRENGTH	NOTES
ANTIPSYCHOTICS, ATYPICAL, DOPAMINE, & SEROTONIN ANTAG	INVEGA TRINZA	PALIPERIDONE PALMITATE	410/1.315	NEW FORMULATION
ANTIPSYCHOTICS, ATYPICAL, DOPAMINE, & SEROTONIN ANTAG	INVEGA TRINZA	PALIPERIDONE PALMITATE	546MG/1.75	NEW FORMULATION
ANTIPSYCHOTICS, ATYPICAL, DOPAMINE, & SEROTONIN ANTAG	INVEGA TRINZA	PALIPERIDONE PALMITATE	819/2.625	NEW FORMULATION
TETRACYCLINES	DORYX	DOXYCYCLINE HYCLATE	50 MG	NEW STRENGTH/DOSAGE FORM
NARCOTIC ANTITUSSIVE-1ST GENERATION ANTIHISTAMINE	TUZISTRA XR	CODEINE POLI/CHLORPHENIRPOLIS	14.7-2.8/5	NEW COMBINATION
BARBITURATES	PHENOBARBITAL	PHENOBARBITAL	20 MG/5 ML	5 ML IN 1 CUP
DILUENT PRODUCTS	DILUENT-MERCK LIVE VIRUS VACC	DILUENT #1, LIV VIRUS VAC(SWFI)	-	WILL NOT PROCESS UNTIL PRICING IS PROVIDED
DILUENT PRODUCTS	DILUENT FOR YF-VAX	DILUENT, YELLW FEV VAC, MDV, NACL	0.9%	WILL NOT PROCESS UNTIL PRICING IS PROVIDED
DILUENT PRODUCTS	DILUENT FOR YF-VAX	DILUENT, YELLOW FEV VAC, SD, NACL	0.9%	WILL NOT PROCESS UNTIL PRICING IS PROVIDED
PRENATAL VITAMIN PREPARATIONS	TRISTART DHA	PRENATAL NO.93/IRON/FA #9/DHA	31-1-200MG	NEW COMBINATION
PEDIATRIC VITAMIN PREPARATIONS	POLY-VI-FLOR FS	PEDI MULTIVIT #90 W-FLUORIDE	0.25 MG	NEW STRENGTH
PKU TX AGENT-COFACTOR OF PHENYLALANINE HYDROXYLASE	KUVAN	SAPROPTERIN DIHYDROCHLORIDE	500 MG	NEW STRENGTH
BETA-ADRENERGIC AND GLUCOCORTICOID COMBINATIONS	BREO ELLIPTA	FLUTICASONE/VILANTEROL	200-25 MCG	NEW STRENGTH
ANTISERA	FLEBOGAMMA DIF	IMM GLOB G (IGG)/SORB/IGA 0-50	5%	NDC MOVE TO NEW GCN
ANTISERA	GAMMAPLEX	IMMUN GLOB G/SORB/GLY/IGA 0-50	5%	NDC MOVE TO NEW GCN
ANTISERA	BIVIGAM	IMMUN GLOB G (IGG)/GLY/IGA 50+	10%	NDC MOVE TO NEW GCN

DESCRIPTION	BRAND NAME	GENERIC NAME	STRENGTH	NOTES
ANTISERA	FLEBOGAMMA DIF	IMMUN GLOB G(IGG)/SORB/IGA 50+	10%	NDC MOVE TO NEW GCN
ANTISERA	GAMMAGARD LIQUID	IMMUN GLOB G (IGG)/GLY/IGA 50+	10%	NDC MOVE TO NEW GCN
ANTISERA	PRIVIGEN	IMMUN GLOB G(IGG)/PRO/IGA 0-50	10%	NDC MOVE TO NEW GCN

## NEW INDICATIONS (EXISTING DRUGS)

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DRUG	NEW INDICATION	DATE OF APPROVAL	LINKS
<b>AVELOX®</b>	TREATMENT OF PNEUMONIC AND SEPTICEMIA PLAGUE	May 8, 2015	Avelox® [package insert]. Bayer Inc, May 2015
<b>TREXIMET®</b>	ACUTE TREATMENT OF MIGRAINE WITH OR WITHOUT AURA IN PEDIATRIC PATIENTS 12 YEARS OF AGE AND OLDER	May 15, 2015	Treximet® [package insert]. Pernix Therapeutics Holdings Inc, May 2015
<b>PROMACTA®</b>	NEW PEDIATRIC CHRONIC IMMUNE THROMBOCYTOPENIA	June 12, 2015	Promacta® [package insert]. GlaxoSmithKline June 2015
<b>ZOMIG®</b>	ACUTE TREATMENT OF MIGRAINE WITH OR WITHOUT AURA IN PEDIATRIC PATIENTS 12 YEARS OF AGE AND OLDER	June 16, 2015	Zomig® [package insert]. AstraZeneca June 2015

## FDA NEWS/BULLETINS/ADVISORIES/SAFETY ALERTS

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### Zerbaxa (ceftolozane and tazobactam): Drug Safety Communication – FDA Cautions About Dose Confusion and Medications Errors

[Posted 05/20/2015]

**ISSUE:** The U.S. Food and Drug Administration (FDA) is warning health care professionals about the risk for dosing errors with the antibacterial drug Zerbaxa (ceftolozane and tazobactam) due to confusion about the drug strength displayed on the vial and carton labeling

FDA evaluated seven reported cases of medication error that occurred during preparation of the dose in the pharmacy due to confusion with the display of the strength of individual ingredients on Zerbaxa's vial labels and carton labeling. Listing the individual drug strengths led to confusion because it was different from labeling for other drugs in the beta-lactam/beta-lactamase class that express strength as the sum of the two active ingredients. In some cases, this led to administration of 50% more drug than was prescribed. No adverse events were reported among these seven cases.

**BACKGROUND:** Zerbaxa is used to treat complicated infections in the urinary tract, or in combination with the antibacterial drug metronidazole to treat complicated infections in the abdomen. Antibacterial drugs work by killing or stopping the growth of bacteria that can cause illness.

**RECOMMENDATION:** FDA urges health care professionals and patients to report side effects and medication errors involving Zerbaxa to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: [www.fda.gov/MedWatch/report.htm](http://www.fda.gov/MedWatch/report.htm)
- 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

**ARTICLE LINK:**

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm447629.htm>



## Injectable Products by Mylan: Recall - Presence of Particulate Matter

[Updated: 06/08/2015]

[Posted: 04/24/2015]

**UPDATE:** Mylan is expanding its voluntary nationwide recall to the hospital/user level of select lots of Gemcitabine for Injection and Methotrexate Injection products due to the presence of visible foreign particulate matter observed during testing of retention samples.

**ISSUE:** Mylan N.V. is conducting a voluntary nationwide recall to the hospital/user level of select lots of injectable products due to the presence of visible foreign particulate matter observed during testing of retention samples.

Administration of a sterile injectable that has foreign particulates has the potential of severe health consequences. Intrathecal administration could result in a life threatening adverse event or result in permanent impairment of a body function. Intravenous administration has the potential to damage and/or obstruct blood vessels which could induce emboli, particularly in the lungs. If a right to left cardiac shunt is present, the particulate may lead to arterial emboli and result in stroke, myocardial infarction, respiratory failure, and loss of renal and hepatic function or tissue necrosis. Other adverse effects associated with intravenous injection of particulate matter include local inflammation, phlebitis, allergic response and/or embolization in the body and infection. Intra-arterial administration could result in damage to blood vessels in the distal extremities or organs. Intramuscular administration could result in foreign-body inflammatory response, with local pain, swelling and possible long term granuloma formation.

**BACKGROUND:** Gemcitabine for Injection, USP 200mg is an intravenously administered product indicated for the treatment of ovarian cancer, breast cancer, non-small cell lung cancer and pancreatic cancer. These lots were distributed in the U.S. between Feb. 18, 2014, and Dec. 19, 2014, and were manufactured and packaged by Agila Onco Therapies Limited, a Mylan company. Lot 7801089 is packaged with a Pfizer Injectable label.

Carboplatin Injection 10mg/mL is an intravenously administered product indicated for the treatment of advanced ovarian carcinoma. The lot was distributed in the U.S. between Aug. 11, 2014, and Oct. 7, 2014, and was packaged by Agila Onco Therapies Limited, a Mylan company, with a Mylan Institutional label.

Methotrexate Injection, USP 25mg/mL can be administered intramuscularly, intravenously, intra-arterially, or intrathecally and is indicated for certain neoplastic diseases, severe psoriasis and adult rheumatoid arthritis. The lot was distributed in the U.S. between Jan. 16, 2014, and March 25, 2014, and was packaged by Agila Onco Therapies Limited, a Mylan company, with a Pfizer Injectables label.

Cytarabine Injection can be administered intravenously or intrathecally and in combination with other approved anti-cancer drugs is indicated for remission induction in acute non-lymphocytic

leukemia of adults and pediatric patients. The lot was distributed in the U.S. between May 02, 2014, and July 24, 2014, and was manufactured and packaged by Agila Onco Therapies Limited, a Mylan company located in Bangalore, India and is packaged with a Pfizer Injectables label.

**RECOMMENDATION:** Mylan is notifying its distributors and customers by letter and is arranging for return of all recalled products. Distributors, retailers, hospitals, clinics, and physicians that have these products which are being recalled should stop use and return to place of purchase. Consumers with questions regarding this recall can contact Mylan Customer Relations at 800.796.9526 or [customer.service@mylan.com](mailto:customer.service@mylan.com), Monday through Friday from 8 a.m. - 5 p.m. EST.

- Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to using these drug products.
- 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)

**ARTICLE LINK:**

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm444517.htm>

**Potiga (ezogabine): Drug Safety Communication - FDA Determines 2013 Labeling Adequate to Manage Risks of Retinal Abnormalities, Potential Vision Loss, and Skin Discoloration [Posted 06/16/2015]**

**ISSUE:** Based on reviews of additional safety reports from patients treated with the anti-seizure drug Potiga (ezogabine), the FDA has determined that the potential risks of vision loss due to pigment changes in the retina and of skin discoloration can be adequately managed by following the current recommendations in the Potiga labeling. To further explore any potential long-term consequences of these pigment changes, FDA has required the Potiga manufacturer, GlaxoSmithKline, to conduct a long-term observational study.

FDA review of additional safety reports does not indicate that the pigment changes in the retina observed in some patients affect vision. Skin discoloration associated with the use of Potiga appears to be a cosmetic effect and does not appear to be associated with more serious adverse effects. Therefore, a modification of the Risk Evaluation and Mitigation Strategy (REMS) is not needed at this time to ensure that the benefits of Potiga outweigh the risks of retinal and skin pigment changes. FDA expects that the required long-term observational study will provide further information on whether pigment changes in the retina caused by Potiga can lead to

vision loss or other long-term side effects. In addition, the study should provide more information on the relationship between pigment changes in the retina and skin discoloration.

**BACKGROUND:** Potiga is approved for use in combination with other anti-seizure drugs to treat partial-onset seizures in adult patients who have had an inadequate response to several alternative therapies and for whom the benefits of treatment outweigh the risks.

**RECOMMENDATION:** Health care professionals should continue to follow the recommendations provided in the Boxed Warning, FDA's most serious type of warning, and the Warnings and Precautions and Indications and Usage sections of the labeling. 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

**ARTICLE LINK:**

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm451181.htm>

## STUDIES and RECENT TOPICS

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### FDA schedules meeting on twice-rejected female libido drug

**May 7, 2015**

The Food and Drug Administration will ask a group of outside medical experts next month to evaluate a much-debated experimental drug designed to boost sexual desire in women. The meeting is the latest twist in the ongoing saga of flibanserin, a proposed female libido pill which the FDA has already twice declined to approve. But the drug's backer, Sprout Pharmaceuticals, has enlisted women's groups and other advocates to lobby the agency to approve the pill, saying women's sexual problems have been too long overlooked by the federal government.

**Article link:**

[http://hosted.ap.org/dynamic/stories/U/US\\_FEMALE\\_SEX\\_PILL?SITE=AP&SECTION=HOME&TEMPLATE=DEFAULT](http://hosted.ap.org/dynamic/stories/U/US_FEMALE_SEX_PILL?SITE=AP&SECTION=HOME&TEMPLATE=DEFAULT)

**Source link:** ap.org

### Scientists May Have Just Found A Solution For Deadly Superbugs

**May 7, 2015**

A computer program designed by two scientists could one day be a weapon in the fight against antibiotic resistance in bacteria. Using complex algorithms, biologist Miriam Barlow of the University of California, Merced and mathematician Kristina Crona of American University in Washington, D.C. were able to prevent and actually reverse antibiotic resistance in a lab setting.

**Article link:** [http://www.huffingtonpost.com/2015/05/07/antibiotic-resistance-software\\_n\\_7228766.html](http://www.huffingtonpost.com/2015/05/07/antibiotic-resistance-software_n_7228766.html)

**Source link:** huffingtonpost.com

### Statins can slow progress of prostate cancer, study finds

**May 7, 2015**

New research suggests statins could slow progress of prostate cancer by 10 months in men with advanced disease. Results from a new trial show that the drugs significantly increase the time it takes for the disease to stop responding to treatment.

**Article link:** <http://www.telegraph.co.uk/news/health/news/11589645/Statins-can-slow-progress-of-prostate-cancer-study-finds.html>

**Source link:** telegraph.co.uk

## Measles Vaccination Saves You From More Than Measles

May 7, 2015

Here's another reason to get vaccinated against measles - researchers have found the measles virus makes kids' immune systems "forget" most of what they have learned, leaving children vulnerable to other diseases for as long as three years. The findings, published in the journal Science, help explain why deaths and illnesses from a range of diseases plummet in countries after they introduce measles vaccine campaigns.

**Article link:** <http://www.nbcnews.com/storyline/measles-outbreak/measles-vaccination-saves-you-more-measles-n355501>

**Source link:** nbcnews.com

## Abuse of Pain Pills Fuels Virus's Spread, Confounding Regulators

May 7, 2015

The abuse of a pain pill from Endo International Plc and its generic copies is being blamed for an increase of hepatitis C among drug addicts -- an unintended consequence of a regulatory decision meant to cut down on misuse.

**Article link:** <http://www.bloomberg.com/news/articles/2015-05-07/abuse-of-pain-pills-fuels-virus-s-spread-confounding-regulators>

**Source link:** bloomberg.com

## Increasing Tysabri Dosing Interval Appears Effective

May 12, 2015

Freedom from relapse was maintained in multiple sclerosis patients on natalizumab (Tysabri) who received the infusion drug less frequently than the recommended 4-week interval, with lower risk of progressive multifocal leukoencephalopathy (PML), preliminary results from an ongoing analysis indicated.

**Article link:** <http://www.medpagetoday.com/Neurology/MultipleSclerosis/51485>

**Source link:** medpagetoday.com

### **New Moms' Codeine Use Down Since Health Warnings** **May 12, 2015**

Fewer new mothers have been prescribed the painkiller codeine since public health officials warned about a rare, but potential risk of overdose for breast-feeding babies, a new study says. Experts said the study results, reported in the May 12 Journal of the American Medical Association, are good news.

**Article link:** [http://consumer.healthday.com/women-s-health-information-34/breast-feeding-news-82/new-moms-codeine-use-down-since-health-warnings-699346.html?utm\\_expid=38353063-4.pIV1hUrQR8K\\_MJ1\\_OqjLag.0](http://consumer.healthday.com/women-s-health-information-34/breast-feeding-news-82/new-moms-codeine-use-down-since-health-warnings-699346.html?utm_expid=38353063-4.pIV1hUrQR8K_MJ1_OqjLag.0)

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

### **A Top Cardiologist Says A Diet Drug Maker Misled Patients And Investors** **May 12, 2015**

A top cardiologist is accusing a drug maker with whom he worked closely of making misleading statements about its weight loss medicine and refusing to release data that would undermine its previous claims.

**Article link:** <http://www.forbes.com/sites/matthewherper/2015/05/12/a-top-cardiologist-says-a-diet-drug-maker-misled-patients-and-investors/>

**Source link:** [forbes.com](http://forbes.com)

### **3D-Printing Oddly Shaped Pills Can Change How Fast They're Absorbed** **May 13, 2015**

Medicine is one of the more exciting fields that 3D printing promises to radically innovate. Doctors have already used the technology to help repair damaged airways in children with a 3D-printed splint, but researchers in the pharmaceutical field have instead been dabbling with custom-shaped pills optimized for every patient's treatment needs.

**Article link:** <http://gizmodo.com/3d-printing-oddly-shaped-pills-can-change-how-fast-they-1704180137>

**Source link:** [gizmodo.com](http://gizmodo.com)

## FDA studying how generics' size, shape and color impact medication adherence

May 14, 2015

When it comes to medication adherence, issues like side effects, cost and ease of intake are most commonly cited issues for noncompliance. But what about the drug's appearance? The Food and Drug Administration is studying how a drug's color, shape and size impact a patient's likelihood to remain on a treatment regimen. The FDA adds that varying pill appearance may also lead to medication errors.

**Article link:** <http://medcitynews.com/2015/05/fda-generics-appearance-study-patient-adherence/>

**Source link:** [medcitynews.com](http://medcitynews.com)

## Generic ADHD Drug Maker Locks Horns With FDA

May 14, 2015

To what extent should the FDA be allowed to reclassify a generic drug when the agency believes it is no longer equivalent to the brand-name version? The issue is being raised in an unusual lawsuit claiming the agency overstepped its bounds by deciding two generic drugs used to treat ADHD should no longer be substituted for the widely used Concerta treatment. And the outcome of the case may have implications for generic drug makers and the FDA.

**Article link:** <http://blogs.wsj.com/pharmalot/2015/05/14/fda-and-mallinckrodt-lock-horns-over-the-right-to-sell-generic-concerta/>

**Source link:** [wsj.com](http://wsj.com)

## FDA warns on newer class of type 2 diabetes drugs

May 15, 2015

The U.S. Food and Drug Administration on Friday warned that a widely used newer class of type 2 diabetes drugs sold by AstraZeneca, Johnson & Johnson and Eli Lilly in partnership with Boehringer Ingelheim may cause dangerously high levels of blood acids that could require hospitalization. The oral drugs belong to a class known as SGLT2 inhibitors, and the FDA warns the medicines may lead to ketoacidosis.

**Article link:** <http://www.reuters.com/article/2015/05/15/us-fda-diabetes-idUSKBN0001P520150515>

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

### **Pill that quashes tobacco urge found in plain sight**

**May 15, 2015**

Rick Stewart didn't know about the laburnum trees growing in Bulgaria — and their potential to produce a drug for quitting smoking — back when he was the chief executive of the pharmaceutical company Amarin. With the help of the National Institutes of Health, Stewart is trying to introduce the laburnum-derived drug to the U.S. market. The pill works by interrupting tobacco cravings.

**Article link:** [http://www.washingtonpost.com/business/economy/pill-promises-a-safer-cheaper-way-than-chantix-to-quit-smoking/2015/05/15/8ce5590c-f830-11e4-9030-b4732caefe81\\_story.html](http://www.washingtonpost.com/business/economy/pill-promises-a-safer-cheaper-way-than-chantix-to-quit-smoking/2015/05/15/8ce5590c-f830-11e4-9030-b4732caefe81_story.html)

**Source link:** [washingtonpost.com](http://washingtonpost.com)

### **Asthma in the City: Rx Adherence Barriers**

**May 19, 2015**

Poverty and poor understanding of the disease undermine adherence. Only about a third of poor inner-city kids are taking asthma medications as prescribed, and in many cases the needed medicine may not even be in the family's medicine cabinet.

**Article link:** <http://www.medpagetoday.com/MeetingCoverage/ATS/51640>

**Source link:** [medpagetoday.com](http://medpagetoday.com)

### **Antidepressants Ease Postpartum Depression, Study Finds**

**May 19, 2015**

But breast-feeding moms should talk with doctor about risks and benefits of drugs, researchers say. Antidepressants seem to help women deal with postpartum depression after childbirth, according to a new review.

**Article link:** [http://consumer.healthday.com/mental-health-information-25/antidepressants-news-723/antidepressants-ease-postpartum-depression-study-699543.html?utm\\_expid=38353063-4.pIV1hUrQR8K\\_MJ1\\_OqjLag.0](http://consumer.healthday.com/mental-health-information-25/antidepressants-news-723/antidepressants-ease-postpartum-depression-study-699543.html?utm_expid=38353063-4.pIV1hUrQR8K_MJ1_OqjLag.0)

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



## Botox Seems To Ease Depression

May 20, 2015

All sorts of science-y sounding brain drugs are used to treat serious depression: serotonin reuptake inhibitors, tricyclic antidepressants, serotonin/neuroepinephrine reuptake inhibitors, atypical antipsychotics, et cetera. But what about using a bacterial toxin that paralyzes your face muscles?

**Article link:**

<http://www.forbes.com/sites/matthewherper/2015/05/20/botox-seems-to-ease-depression/?ss=pharma-healthcare>

**Source link:** forbes.com

## The FDA Approves a Major New Anti-Aging Treatment

June 4, 2015

There's an old adage that if you want to know a woman's real age, look at her hands. That may be less reliable now that the FDA announced its approval today of the first injectable filler for hands. The injectable, Radiesse, was first cleared by the FDA in 2006 to fill smile lines. It won approval for use in the back of the hands based on a one-year trial of more than 100 patients in several sites around the country. At three months, 98 percent of patients in the study reported improved appearance.

**Article link:** Company server won't allow me to visit site

**Source link:** allure.com

## Withholding ARBs After Surgery Linked to Higher Mortality

June 4, 2015

For veterans regularly prescribed angiotensin receptor blockers (ARBs) admitted for noncardiac surgery, failure to resume ARB therapy by postoperative day two is associated with increased mortality risk, according to a study published online May 30 in Anesthesiology.

**Article link:** <http://www.physiciansbriefing.com/Article.asp?AID=700037>

**Source link:** physiciansbriefing.com

### **Studies: Widely used diabetes drugs seem safe for the heart**

**June 8, 2015**

Some widely used diabetes medicines help control blood sugar without the heart risks suggested by earlier research, new studies find. Although reassuring on safety, the results disappointed some doctors who had hoped the drugs would do better and help prevent heart problems, the top cause of death for people with diabetes.

**Article link:** <http://news.yahoo.com/studies-widely-used-diabetes-drugs-seem-safe-heart-203331748.html>

**Source link:** yahoo.com

### **FDA Approves Edible Medicine For Kids With HIV That Will Save More Young Lives**

**June 9, 2015**

The U.S. Food and Drug Administration approved an edible antiretroviral formulation for children who have HIV, UNICEF reported last Friday. The move will result in increased access to the vital medicine in developing regions and will save more young lives, according to the humanitarian group.

**Article link:** [http://www.huffingtonpost.com/2015/06/09/hiv-treatment-save-lives\\_n\\_7537118.html](http://www.huffingtonpost.com/2015/06/09/hiv-treatment-save-lives_n_7537118.html)

**Source link:** huffingtonpost.com

### **Clinicians reluctant to prescribe medication that counteracts effects of opioid overdose**

**June 9, 2015**

A variety of factors including questions about risk and reluctance to offend patients limits clinician willingness to prescribe a potentially life-saving medication that counteracts the effects of an opioid overdose, according to a Kaiser Permanente Colorado study published today in the Journal of General Internal Medicine.

**Article link:** <http://medicalxpress.com/news/2015-06-clinicians-reluctant-medication-counteracts-effects.html>

**Source link:** medicalxpress.com

### **Stanford 'Big Data' Study Links Common Heartburn Drugs with Heart Attack Risk** **June 10, 2015**

Some of the most commonly used drugs in the world to treat heartburn are associated with a 16 to 20 percent increased risk of heart attack, a large data mining study of electronic health records from Stanford researchers shows.

**Article link:** <http://ww2.kqed.org/stateofhealth/2015/06/10/stanford-big-data-study-links-common-heartburn-drugs-with-heart-attack-risk/>

**Source link:** [kqed.org](http://kqed.org)

### **ADA: Glucagon Nasal Powder Effective for Kids** **June 10, 2015**

Glucagon in the form of nasal powder was effective in managing hypoglycemia in children and teens with type 1 diabetes, said a researcher here. The glucagon nasal powder (GNP) comes in a single-use device that injects into a patient's nose, entering the body through the mucus. In the cohort of 48 patients ages 4 to 17, GNP was found to have similar efficacy to injected glucagon in the study which was presented at a poster session at the annual meeting of the American Diabetes Association here.

**Article link:** <http://www.medpagetoday.com/MeetingCoverage/ADA/52050>

**Source link:** [medpagetoday.com](http://medpagetoday.com)

### **Lab study: Daily aspirin could block growth of breast, other cancers** **June 11, 2015**

"Take two aspirin and call me in the morning" has been the punchline for countless jokes. Could it also be good advice for cancer patients? A lab study to appear in the July 2015 issue of Laboratory Investigation found that a daily dose of aspirin was effective at blocking breast tumor growth. Previous studies have already shown a similar effect on colon, gastrointestinal, prostate, and other cancers.

**Article link:** [http://www.eurekalert.org/pub\\_releases/2015-06/varc-lsd061115.php](http://www.eurekalert.org/pub_releases/2015-06/varc-lsd061115.php)

**Source link:** [eurekalert.org](http://eurekalert.org)

### **FDA Mistakenly Widened the Market for a Rare Sleep Disorder Drug: Petition** **June 11, 2015**

Early last year, the FDA approved a drug called Hetlioz to treat non-24 sleep-wake disorder, a rare condition that throws off the internal body clock and causes sleeping problems. But a

consumer advocacy group says the agency goofed and may have inadvertently widened the market for the drug by omitting language from the label indicating it was intended only for patients who are also blind.

**Article link:** <http://blogs.wsj.com/pharmalot/2015/06/11/fda-mistakenly-widened-the-market-for-a-rare-sleep-disorder-drug-petition/>

**Source link:** [wsj.com](http://www.wsj.com)

### **Sleeping Pill Use Raises Car Crash Risk, Study Finds**

**June 11, 2015**

Sleeping pills such as Ambien and Restoril may double someone's risk of a car crash — even after their effects should have worn off — and may raise the risk as much as having too much to drink, researchers reported Thursday.

**Article link:** <http://www.nbcnews.com/health/health-news/sleeping-pills-raise-car-crash-risk-study-finds-n373891>

**Source link:** [nbcnews.com](http://www.nbcnews.com)

### **Could ADHD Drug Find New Role in Menopause?**

**June 12, 2015**

A drug marketed for attention deficit hyperactivity disorder might improve memory and concentration problems associated with menopause, a new, small study suggests. Vyvanse (lisdexamfetamine), a stimulant, is usually prescribed to children and adults with ADHD. But researchers found it also may help to improve menopausal women's "executive function" -- brain activities such as memory, reasoning, multitasking, planning and problemsolving.

**Article link:** <http://consumer.healthday.com/kids-health-information-23/attention-deficit-disorder-adhd-news-50/adhd-drug-may-find-new-role-in-menopause-700348.html>

**Source link:** [healthday.com](http://www.healthday.com)

### **An old-line diabetes drug may have new uses against diseases of aging**

**June 15, 2015**

Just over a year ago, Catherine Price decided to start taking one of the cheapest, safest, oldest, most widely prescribed drugs for Type 2 diabetes. So much metformin is taken in the United States — some 72 million prescriptions were written for it in 2013 — that a recent study found higher trace levels of it (presumably from the urine of people taking it) in Lake Michigan than of any other drug, including caffeine.

**Article link:** [http://www.washingtonpost.com/national/health-science/an-old-line-diabetes-drug-may-have-new-uses-against-diseases-of-aging/2015/06/15/6a16e83c-0a0f-11e5-9e39-0db921c47b93\\_story.html](http://www.washingtonpost.com/national/health-science/an-old-line-diabetes-drug-may-have-new-uses-against-diseases-of-aging/2015/06/15/6a16e83c-0a0f-11e5-9e39-0db921c47b93_story.html)

**Source link:** [washingtonpost.com](http://washingtonpost.com)

### **Generic A.D.H.D. Drug, Not Equivalent to the Brand, Is in Use Anyway**

**June 16, 2015**

When Dr. Louis Kraus, a chief of child psychiatry at a hospital in Chicago, writes prescriptions for patients who have attention-deficit hyperactivity disorder, he often chooses Concerta, an extended-release form of the drug Ritalin that gives patients relief from their symptoms for as long as 12 hours.

**Article link:** [http://www.nytimes.com/2015/06/17/business/generic-ritalin-drug-not-equivalent-to-the-brand-is-in-use-anyway.html?ref=health&\\_r=1](http://www.nytimes.com/2015/06/17/business/generic-ritalin-drug-not-equivalent-to-the-brand-is-in-use-anyway.html?ref=health&_r=1)

**Source link:** [nytimes.com](http://nytimes.com)

### **Report: Drug overdose death rates increase in 26 states**

**June 18, 2015**

Drug overdose death rates have increased in 26 states and Washington, D.C., and overdoses continue to outpace car crashes as the leading cause of injury-related deaths, according to a new report. Nearly 44,000 people die from drug overdoses each year, a figure that more than doubled from 1999 to 2013, and more than half of them stem from prescription pills.

**Article link:** <http://www.usatoday.com/story/news/nation/2015/06/17/injury-report-drug-overdose/28873891/>

**Source link:** [usatoday.com](http://usatoday.com)

## RECALLS\*

Product type	Product description	Code info.	Class	Reason for recall	Recalling firm
<b>CLASS I</b>					
Drugs	Lactated ringer's irrigation, usp, 3000 ml flexible container bag, rx only	Lot # 40-008-jt; exp. 04/01/16	Class I	Non-sterility: confirmed customer report of dark, fibrous particulates floating within the solution of the primary container, which were subsequently identified as mold	Hospira inc.
Drugs	Testosterone cypionate 200 mg/ml in sesame oil, 10 ml amber glass vial, rx only	Lot # t-1201s14, exp 5/30/2015	Class I	Incorrect product formulation: vials labeled as testosterone cypionate 200 mg/ml in sesame oil are being recalled because they contains estradiol valerate 20 mg/ml.	Stroheckers inc pharmacy
<b>CLASS II</b>					
Drugs	Acarbose tablets 50 mg a)10 x 10 unit dose tablets per blister pack, b)100 count bottles, rx only	A) lot # 460073a exp 04/2016 b) lot # 460073b exp 04/2016	Class II	Subpotent drug: the firm received an out of specification result for assay (potency was below specification) at the 9 month stability time point.	Boehringer ingelheim roxane inc
	Daytrana (methylphenidate transdermal system), delivers 30 mg over 9 hours (3.3mg/hr), cii, 30 patches per box	Lot # 73346, exp 03/2015	Class II	Defective delivery system: one lot exceeded the mechanical peel specification. Nineteen lots were withdrawn due to out-of-trend results.	Noven pharmaceuticals, inc.
Drugs	Cyanocobalamin (paraben water) (10ml, 30ml vial) 2000mcg/ml injectable	All lots	Class II	Lack of assurance of sterility	Advanced physician solutions, inc.

Product type	Product description	Code info.	Class	Reason for recall	Recalling firm
Drugs	Estradiol cypionate (sesame oil) 10ml, 30ml vial 5mg/ml injectable	All lots	Class II	Lack of assurance of sterility	Advanced physician solutions, inc.
Drugs	Estradiol valerate (10ml vial) sesame oil 45mg/ml injectable	All lots	Class II	Lack of assurance of sterility	Advanced physician solutions, inc.
Drugs	Estradiol valerate (sesame oil) 10ml vial 10mg/ml injectable	All lots	Class II	Lack of assurance of sterility	Advanced physician solutions, inc.
Drugs	Glutathione 200mg/ml (sterile water) (30ml, 50ml vial) injectable	All lots	Class II	Lack of assurance of sterility	Advanced physician solutions, inc.
Drugs	Glycerin (sterile water) 100ml 71% injectable	All lots	Class II	Lack of assurance of sterility	Advanced physician solutions, inc.
Drugs	Hydroxyprogesterone caproate (olive oil) 30ml, 10ml vial 250mg/ml injectable	All lots	Class II	Lack of assurance of sterility	Advanced physician solutions, inc.
Drugs	Hydroxyzine hydrochloride (30ml vial) (sterile water) 50mg/ml injectable	All lots	Class II	Lack of assurance of sterility	Advanced physician solutions, inc.
Drugs	Hydroxyzine hydrochloride (sterile water) (10ml vial) 25mg/ml injectable	All lots	Class II	Lack of assurance of sterility	Advanced physician solutions, inc.
Drugs	Nandrolone decanoate (sesame oil) 100ml vial 200mg/ml injectable	All lots	Class II	Lack of assurance of sterility	Advanced physician solutions, inc.
Drugs	Nanpyridoxine (sterile water) 30ml 50mg/ml injectable	All lots	Class II	Lack of assurance of sterility	Advanced physician solutions, inc.
Drugs	Sodium hyaluronate (2ml prefilled syringe) sterile water 20mg/ml injectable	All lots	Class II	Lack of assurance of sterility	Advanced physician solutions, inc.
Drugs	Sodium hyaluronate (sterile water) 2.5 ml vial 20mg/ml injectable	All lots	Class II	Lack of assurance of sterility	Advanced physician solutions, inc.
Drugs	Sodium tetradecyl (sterile water) 30ml vial 2% injectable	All lots	Class II	Lack of assurance of sterility	Advanced physician solutions, inc.
Drugs	Sodium tetradecyl sulfate (sterile water) (30ml) 3.5%	All lots	Class II	Lack of assurance of sterility	Advanced physician

Product type	Product description	Code info.	Class	Reason for recall	Recalling firm
	injectable				solutions, inc.
Drugs	Vitamin d3 (olive oil) (30ml vial) 50,000 units/ml injectable	All lots	Class II	Lack of assurance of sterility	Advanced physician solutions, inc.
Drugs	Dmso (sterile water) solution -50ml vial 50% injectable	All lots	Class II	Lack of assurance of sterility	Advanced physician solutions, inc.
Drugs	Estradiol cypionate (sesame oil) (10ml, 30ml vial) 40mg/ml injectable	All lots	Class II	Lack of assurance of sterility	Advanced physician solutions, inc.
Drugs	Captopril tablets, usp, 50 mg, 30 tablets, rx only	Lot bp20101301, exp. Date 02/28/2016	Class II	Cgmp deviations; products being recalled in response to a recall notice from the manufacturer, wockhardt limited, following a fda inspection which noted inadequate investigation of market complaints, resulting in unsuccessful identification of root causes, and the investigation not being expanded to prevent repeat failure	Blenheim pharmacal, inc.
Drugs	Clarithromycin tablets, usp, 500 mg, 20 tablets, rx only	Lot bp18181301, exp. Date 02/29/2016	Class II	Cgmp deviations; products being recalled in response to a recall notice from the manufacturer, wockhardt limited, following a fda inspection which noted inadequate investigation of market complaints, resulting in unsuccessful	Blenheim pharmacal, inc.



Product type	Product description	Code info.	Class	Reason for recall	Recalling firm
				identification of root causes, and the investigation not being expanded to prevent repeat failure	
Drugs	Mycophenolic acid delayed-release tablets, 180 mg, 120-count bottle, rx only	Lot #: 3059043, exp 08/16	Class II	Failed dissolution specifications: low out of specification dissolution results.	Mylan lab inc
Drugs	Kabiven [(3.9%) lipid injectable emulsion with (3.1%) amino acids and electrolytes and (9.8%) dextrose; sulfite-free], rx only packaged in 1) 1,540 ml bags and 2) 2,053 ml bags	1) lot # 10hh8781, expiry: 07-2016; 2) lot # 10hh8739, expiry: 07-2016.	Class II	Labeling: label error on declared strength: labeled 3.1% amino acids but contains 3.3% amino acids	Fresenius kabi usa, llc
Drugs	Zebeta® (bisoprolol fumarate), tablets, 10mg, 30-count bottle, rx only	Lot #: 34019710a, exp 5/2017	Class II	Failed dissolution specifications: oos result during stability testing	Teva pharmaceutical s usa
Drugs	Sucrets sore throat & cough vapor cherry lozenges, 18-count tin	Lot #: 42451, exp 09/17	Class II	Labeling: label mix-up: an incorrect book label for sucrets sore throat, cough & dry mouth honey lemon lozenges was applied to the underside of the sucrets sore throat & cough vapor cherry lozenges tin.	Medtech products, inc.
Drugs	Hydroxyzine Hydrochloride, oral solution, 10 mg per 5 mL, 16 fl oz (473 ml) bottle, Rx only	Lot# 621637, 621640 Exp 05/2015; 622748, 622751 Exp 08/2015; 623599, 623602 Exp 09/2015; 624132, 624135 Exp 10/2015;	Class II	Failed Impurities/Degradation Specifications	Akorn, Inc.

Product type	Product description	Code info.	Class	Reason for recall	Recalling firm
		628282, 628285, 628288, 628291 Exp 06/2016; 628850, 628853, 628856, 628859 Exp 07/2016, 629797, 629800, 629803, 629806 Exp 09/2016			
Drugs	Hydroxyzine Hydrochloride, oral solution, 10 mg per 5 mL, 16 fl oz (473 ml) bottle, Rx only	Lot# 620984, 620987, Exp 04/2015; 621481, 621484, 621752, 621754 Exp 05/2015; 621875, 622239 Exp 06/2015; 622742, 622745, 623371 Exp 08/2015; 623374, 623820, 623823 Exp 09/2015; 624265, 624268 Exp 10/2015; 624824, 624827 Exp 11/2015; 625472, 625475 Exp 01/2016; 625783, 625786,	Class II	Failed Impurities/Degradati on Specifications	Akorn, Inc.

Product type	Product description	Code info.	Class	Reason for recall	Recalling firm
		626447, 626450 02/2016; 627683, 627797 Exp 05/2016; 627800 Exp 06/2016; 629094, 629097, 629100, 629103 Exp 08/2016; 629928 Exp 09/2016; 629931, 630480, 630483 Exp 10/2016; 630874, 630877, 631513 Exp 12/2016			
Drugs	PHENYLEphrine HCl 50 mg in 0.9% Sodium Chloride 250 mL bag (Concentration = 0.2 mg per mL), Rx only	Lot: 20150423@47, Exp 07/22/15	Class II	Labeling: Label Mix-Up: Product is incorrectly labeled as phenylephrine 50 mg in 0.9% sodium chloride rather than phenylephrine 50 mg in 5% dextrose.	SCA Pharmaceuticals
Drugs	MD-Gastroview (Diatrizoate Meglumine and Diatrizoate Sodium Solution USP); 37% Organically Bound Iodine For Gastrointestinal Radiography; Oral or rectal use only	Lot #: B201B, Exp April 2015; B346D, Exp August 2015.	Class II	Labeling: incorrect or missing lot number and/or expiration date	Mallinckrodt, Inc.
Drugs	Alprostadil (PFE1), Solution, 10 mcg/mL, injectable, 5 mL vial, Rx only	Lot 03252015:61@6, expiry date: 7/23/2015	Class II	Lack of Assurance of Sterility; objectionable conditions observed during a FDA inspection	Montana Compounding Pharmacy

Product type	Product description	Code info.	Class	Reason for recall	Recalling firm
Drugs	Alprostadil (PFE1), solution, 20 mcg/mL, injectable, 5 mL vial, Rx only	Lot 04022015:93@10, expiry date: 7/31/2015;	Class II	Lack of Assurance of Sterility; objectionable conditions observed during a FDA inspection	Montana Compounding Pharmacy
Drugs	Avastin, solution, 1.25 mg/0.05mL, Injectable, Syringe, Rx only	Lot 04202015:49@1, Expiry date: 5/20/2015; Lot 04272015:06@6, Expiry date: 6/2/2015; Lot 04282015:16@13, Expiry date: 6/12/2015; Lot 05062015:56@3, Expiry date: 5/24/2015;	Class II	Lack of Assurance of Sterility; objectionable conditions observed during a FDA inspection	Montana Compounding Pharmacy
Drugs	Bimix (PHENT;PAP) (N), solution, (10/300) 1 - 30 mg/mL, injectable, 5ml vial, Rx only	Lot 04102015:18@15, expiry date: 7/3/2015	Class II	Lack of Assurance of Sterility; objectionable conditions observed during a FDA inspection	Montana Compounding Pharmacy
Drugs	Glutathione INHALATION (PF), solution, 100mg/mL, 4 mL vial, Rx only	Lot 04102015:70@12; expiry date 5/28/2015.	Class II	Lack of Assurance of Sterility; objectionable conditions observed during a FDA inspection	Montana Compounding Pharmacy
Drugs	Glutathione INHALATION (PF), NASAL solution, 100 mg/mL, 3 mL vial, Rx only	Lot 04102015:36@11, expiry date: 5/29/2015	Class II	Lack of Assurance of Sterility; objectionable conditions observed during a FDA inspection	Montana Compounding Pharmacy
Drugs	Hyaluronidase (RM ONLY), Injectable Solution, 150 U/mL, 10ML vial, Rx Only	Lot 02062015:06@3, expiry date: 5/17/2015; Lot 02272015:93@1, expiry date: 6/30/2015; Lot	Class II	Lack of Assurance of Sterility; objectionable conditions observed during a FDA inspection	Montana Compounding Pharmacy

Product type	Product description	Code info.	Class	Reason for recall	Recalling firm
		03252015:92@7, expiry date: 6/30/2015; Lot 04162015:63@7, expiry date: 6/30/2015.			
Drugs	Trimix (A;PH,PA) (N), injectable, 80 UG-0.6 mg-4.8 mg/mL, 1 mL vial, Rx only	Lot 04162015:77@4, Expiry date: 6/8/2015	Class II	Lack of Assurance of Sterility; objectionable conditions observed during a FDA inspection	Montana Compounding Pharmacy
Drugs	Trimix (A;PH,PA) (N), injectable, 160 UG-1.2 mg-9.6/ mg/mL, 2 mL vial, Rx only	Lot 02112015:78@15, expiry dates: 6/1/2015; Lot 04062015:03@9, expiry dates: 6/8/2015	Class II	Lack of Assurance of Sterility; objectionable conditions observed during a FDA inspection	Montana Compounding Pharmacy
Drugs	Trimix (PGE1;PHENT;PAP) (N), injectable, (100/10/240) 10UG, 5 mL vial, Rx only	Lot 03112015:17@5; Expiry date: 6/1/2015; Lot 04042015:61@2; Expiry date: 6/3/2015; Lot 05022015:11@2; Expiry date: 6/16/2015;	Class II	Lack of Assurance of Sterility; objectionable conditions observed during a FDA inspection	Montana Compounding Pharmacy
Drugs	Trimix (PGE1;PHENT;PAP) (N), injectable, (100/10/297) 10UG, 5 mL vial, Rx only	Lot 04082015:49@7; expiry date: 6/18/2015; Lot 04222015:25@8; expiry date: 7/3/2015.	Class II	Lack of Assurance of Sterility; objectionable conditions observed during a FDA inspection	Montana Compounding Pharmacy
Drugs	Alprostadil (PFE1), solution, 30 mcg/mL, injectable, 5 mL vial, Rx only	Lot 04062015:18@1. Expiry date: 8/1/2015	Class II	Lack of Assurance of Sterility; objectionable conditions observed during a FDA inspection	Montana Compounding Pharmacy
Drugs	Nifedipine Extended-	Lot #: 1309T27;	Class II	Failed Dissolution	Valeant

Product type	Product description	Code info.	Class	Reason for recall	Recalling firm
	Release Tablets, USP, 90 mg, 100 Tablet Bottles, Rx Only	Expiry: 8/15; Lot #: 1309T28, Expiry: 8/15; Lot #: 1311T33, Expiry: 10/15; Lot #: 1311T34, Expiry: 10/15, Lot #: 1312T40, Expiry: 11/15; Lot #: 1312T41, Expiry: 11/15; Lot #: 1403T23, Expiry: 02/16; Lot #: 1403T21, Expiry: 02/16; Lot #: 1405T21, Expiry: 04/16; Lot #: 1405T22, Expiry: 04/16.		Specifications: High dissolution at 1 hour time point	Pharmaceuticals North America LLC
Drugs	Heparin Sodium and 0.9% Sodium Chloride Injection, 1000 USP Heparin Units, 500 mL in a VIAFLEX Plus Container, Rx Only	Product Code: 280953 Lots: N002998 and N003004 exp 12/31/15; and lot N003038 exp. 01/31/2016	Class II	Subpotent Drug; out of specification results for heparin raw material	Baxter Healthcare Corp
<b>CLASS III</b>					
Drugs	Fexofenadine hydrochloride tablets, usp 60 mg, allergy, non-drowsy, antihistamine, 100 tablets (10 x 10) per ud cartons	Lot #: 3051728, 3053762, exp. 4/2015	Class III	Failed impurities/degradation specifications: the manufacturer recalled product due to slightly above specification results for a related compound during routine stability testing	Mylan institutional, inc. (d.b.a. Udl laboratories)
Drugs	Improvue ophthalmic lubricant drops (1.7% hypromellose), 1 single use syringe, 0.07 fl oz (2ml), 1 single use	Lot# v0814b, exp 02/16 and v1014h, exp 04/16	Class III	Failed ph specification	Oasis medical, inc.

Product type	Product description	Code info.	Class	Reason for recall	Recalling firm
	applicator tip per carton				
	Qvar (beclomethasone dipropionate hfa 40 mcg), 40 mcg inhalation aerosol, for oral inhalation with qvar actuator only, 120 metered inhalations, rx only	Lot #:130449, 130450; exp. Date: 12/2015	Class III	Failed impurities/degradation specifications: out of specification test results for an impurity during stability testing.	Teva pharmaceuticals usa
Drugs	Cetirizine hcl chewable tablet, 10 mg, 6-tablets in one blister, in 12 (2 blisters) and 24 (4 blisters) tablet count configurations.	Lot #: dp3841, dp5237, dp5238, dp5238a, dp5238b exp 05/2015; dr7807, dr9954, dr9959, dv5838, exp 07/2015.	Class III	Failed impurities/degradation specifications: an out of specification (oos) result was reported for impurity at the 21 month stability time point.	Sandoz, inc
<b>Vaccines</b>					
Biologics	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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### Hydralazine Injection

May 21, 2015

#### Reason for the Shortage

- Akorn has hydralazine injection on shortage due to increased demand.
- American Regent has hydralazine injection on shortage due to manufacturing delays.
- Fresenius Kabi has hydralazine injection on shortage due to manufacturing delays.

#### Article Link:

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

**Source Link:** <http://www.ashp.org>

### Ondansetron Injection

May 22, 2015

#### Reason for the Shortage

- AuroMedics did not provide a reason for the shortage.
- Caraco temporarily discontinued ondansetron injection.
- Ben Venue stopped production in its plant in Bedford, Ohio and closed in July, 2014.
- Fresenius Kabi has ondansetron injection on back order due to increased demand.
- Heritage cannot provide a reason for the shortage.
- Sagent has ondansetron on back order due to increased demand.
- Teva re-launched ondansetron 20 mL injection in 2015.
- West-Ward had ondansetron on back order due to increased demand.
- Wockhardt has ondansetron injection on an FDA import alert.
- All presentations of ondansetron 32 mg/50 mL premixed bags have been discontinued.

#### Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1040>

**Source Link:** <http://www.ashp.org>

### Ketorolac Tromethamine Injection

May 22, 2015

#### Reason for the Shortage

- Fresenius Kabi states the shortage was due to manufacturing delays.
- Hospira has ketorolac on shortage due to manufacturing delays for quality improvement activities and increased demand for the product.



- Hospira issued a voluntary recall of several presentations of ketorolac in January 2015 due to potential for particulate matter.
- Sagent states the reason for the shortage is demand exceeding supply.
- West-Ward has ketorolac injection on shortage due to manufacturing delays.
- 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.

**Article Link:**

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

**Source Link:** <http://www.ashp.org>

**Cefuroxime Sodium Injection**

**May 22, 2015**

**Reason for the Shortage**

- Sagent states manufacture of cefuroxime 1.5 gram was suspended in March, 2013. No further production is planned.
- Hospira discontinued cefuroxime 1.5 gram and 7.5 gram vials in January, 2013.
- BBraun discontinued their cefuroxime solution in December 2013.
- Fresenius Kabi discontinued manufacturing cefuroxime in 2013.

**Article Link:**

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=990>

**Source Link:** <http://www.ashp.org>

**Valproate Sodium Injection**

**May 26, 2015**

**Reason for the Shortage**

- Fresenius Kabi states the reason for the shortage is manufacturing delay.
- West-Ward could not provide a reason for the shortage.

**Article Link:**

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=990>

**Source Link:** <http://www.ashp.org>

## Potassium Chloride Injection

May 26, 2015

### Reason for the Shortage

- Hospira states the reason for the shortage is manufacturing delays.
- Fresenius Kabi and Baxter could not provide a reason for the shortage.

### Article Link:

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

**Source Link:** <http://www.ashp.org>

## Testosterone Cypionate Intramuscular Injection

May 27, 2015

### Reason for the Shortage

- Actavis discontinued testosterone cypionate injection in 2015.
- Paddock has testosterone on shortage due to increased demand and shipping delays from their contract manufacturer.
- West-Ward had testosterone cypionate on shortage due to manufacturing delays.
- Sandoz discontinued testosterone cypionate 200 mg/mL 1 mL and 10 mL vials in September 2011. Sandoz discontinued final presentation in first half of 2012.
- Sun Pharmaceuticals could not provide a reason for the shortage.

### Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=638>

**Source Link:** <http://www.ashp.org>

## Chloroquine Tablets

May 27, 2015

### Reason for the Shortage

- Global Pharmaceuticals discontinued chloroquine tablets in 2014.
- Rising discontinued chloroquine tablets in February 2015.
- Ranbaxy has chloroquine tablets on shortage due to third party supply issues.
- West-Ward cannot provide a reason for the shortage.

### Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1178>

**Source Link:** <http://www.ashp.org>

## Adenosine Injection

May 27, 2015

### Reason for the Shortage

- Astellas discontinued Adenoscan in April 2015. Adenoscan is used for diagnostic purposes as an adjunct to thallium-201 myocardial perfusion scintigraphy. Adenocard and generic adenosine products are labeled for use in paroxysmal supraventricular tachycardia.
- Ben Venue has stopped production in its plant in Bedford, Ohio and closed in July 2014.
- Sagent has adenosine vials on shortage due to increased demand..
- Teva discontinued their adenosine 3 mg/mL 2 mL and 4 mL presentations.
- West-Ward could not provide a reason for the shortage.
- Wockhardt discontinued their adenosine 3 mg/mL 2 mL and 4 mL syringes.

### Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=976>

**Source Link:** <http://www.ashp.org>

## Sincalide Injection

May 28, 2015

### Reason for the Shortage

- Bracco Diagnostics has Kinevac on shortage due to manufacturing delays.
- There are no approved alternatives to Kinevac for the labeled indications.

### Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1032>

**Source Link:** <http://www.ashp.org>

## Secretin Injection

May 28, 2015

### Reason for the Shortage

- ChiRhoClin is qualifying a manufacturing site.
- ChiRhoClin has been working with FDA to release ChiRhoStim lot # 0636149. This lot was produced at a new manufacturing site that has not been approved by FDA. Please see the Dear Health Care Provider letter for additional information. ChiRhoClin anticipates the release of a new ChiRhoStim lot in 2015.

### Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=913>

**Source Link:** <http://www.ashp.org>

### **Pantoprazole Injection**

**May 29, 2015**

#### **Reason for the Shortage**

- Pfizer has Protonix on shortage due to increased demand.
- Pfizer is the sole supplier of pantoprazole injection.

#### **Article Link:**

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1153>

**Source Link:** <http://www.ashp.org>

### **Magnesium Sulfate Injection**

**May 29, 2015**

#### **Reason for the Shortage**

- American Regent has magnesium sulfate on shortage due to manufacturing delays.
- Fresenius Kabi has magnesium sulfate injection on shortage due to increased demand for the product.
- Hospira has magnesium sulfate injection on shortage due to manufacturing delays.

#### **Article Link:**

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

**Source Link:** <http://www.ashp.org>

### **Fomepizole Injection**

**May 29, 2015**

#### **Reason for 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 could not provide a reason for the shortage.
- Mylan Institutional could not provide a reason for the shortage.

#### **Article Link:**

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1173>

**Source Link:** <http://www.ashp.org>

## Vancomycin Hydrochloride Injection

June 01, 2015

### Reason for the Shortage

- Hospira has vancomycin on shortage due to increased demand.
- Fresenius Kabi has vancomycin injection on shortage due to increased demand.
- Mylan Institutional cannot provide a reason for the shortage.
- Baxter is allocating vancomycin.
- Sagent has vancomycin injection on allocation due to increased demand.

### Article Link:

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

**Source Link:** <http://www.ashp.org>

## Sodium Chloride Concentrated Solution for Injection

June 01, 2015

### Reason for the Shortage

- American Regent discontinued 23.4% sodium chloride 30 mL and 100 mL presentations in 2012.
- Baxter discontinued their sodium chloride 250 mL presentation in 2008.
- Fresenius Kabi has sodium chloride concentrated solution on shortage due to increased demand. Fresenius Kabi discontinued 14.6% sodium chloride 20 mL vials in February 2013.
- Hospira has 14.6% and 23.4% sodium chloride solutions for injection on shortage due to manufacturing delays. Hospira discontinued sodium chloride 14.6% solution 250 mL vials in February 2011.

### Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=724>

**Source Link:** <http://www.ashp.org>

## Promethazine Injection

June 01, 2015

### Reason for 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.

### Article Link:

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

**Source Link:** <http://www.ashp.org>

### **Oxytocin Injection**

**June 01, 2015**

#### **Reason for the Shortage**

- Fresenius Kabi states the shortage was due to increased demand.
- Par Sterile Products (formerly JHP) discontinued generic oxytocin injection in July 2014.
- West-Ward cannot provide a reason for the shortage.

#### **Article Link:**

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

**Source Link:** <http://www.ashp.org>

### **Nicardipine Hydrochloride Injection**

**June 01, 2015**

#### **Reason for the Shortage**

- American Regent has nicardipine injection on shortage due to manufacturing delays.
- Caraco could not provide a reason for the shortage.
- Chiesi acquired Cornerstone Therapeutics and changed the companies name in 2014. Cardene ampules were discontinued in March 2014.
- Mylan Institutional could not provide a reason for the shortage.
- Sandoz could not provide a reason for the shortage.
- Wockhardt has nicardipine on shortage due to an FDA import alert.

#### **Article Link:**

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=31>

**Source Link:** <http://www.ashp.org>

### **Haloperidol Lactate Injection**

**June 01, 2015**

#### **Reason for the Shortage**

- Mylan Institutional could not provide a reason for the shortage.
- Patriot Pharmaceuticals states the reason for the shortage was increased demand.
- Sagent could not provide a reason for the shortage.
- 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.

**Article Link:**

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=527>

**Source Link:** <http://www.ashp.org>

**Disopyramide Phosphate Controlled-release Capsules**

**June 01, 2015**

**Reason for the Shortage**

- Pfizer has Norpace CR on shortage due to manufacturing delays.

**Article Link:**

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1139>

**Source Link:** <http://www.ashp.org>

**Diltiazem Injection**

**June 01, 2015**

**Reason for the Shortage**

- Ben Venue stopped production in its plant in Bedford, Ohio and closed in July 2014.
- 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.
- Akorn states the reason for the shortage is increased demand due to market conditions.
- Teva discontinued all diltiazem presentations in March, 2011.
- Biovail discontinued Cardizem Lyo-Ject in 2007 due to business reasons.

**Article Link:**

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=217>

**Source Link:** <http://www.ashp.org>

**Bupivacaine Injection**

**June 01, 2015**

**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.
- AuroMedics introduced bupivacaine injection in February 2014.

**Article Link:**

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

**Source Link:** <http://www.ashp.org>

**Morrhuate Sodium Injection**

**June 02, 2015**

**Reason for the Shortage**

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

**Article Link:**

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=903>

**Source Link:** <http://www.ashp.org>

**Lidocaine Injection**

**June 02, 2015**

**Reason for the Shortage**

- Amphastar had lidocaine 2% emergency syringes on shortage due to increase demand for the product.
- AuroMedics introduced lidocaine injection in February 2014.
- Fresenius Kabi has Xylocaine and lidocaine presentations on shortage due to increased demand for the product.
- Hospira has lidocaine presentations on shortage due to manufacturing delays and increased demand.

**Article Link:**

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=859>

**Source Link:** <http://www.ashp.org>

**Acamprosate Calcium Tablets**

**June 02, 2015**

**Reason for the Shortage**

- Glenmark Pharmaceuticals cannot provide a reason for the shortage.
- Mylan cannot provide a reason for the shortage.



- Actavis discontinued Campral tablets in 2014.

**Article Link:**

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1170>

**Source Link:** <http://www.ashp.org>

**Vecuronium Bromide Injection**

**June 03, 2015**

**Reason for the Shortage**

- Hospira states the shortage is due to manufacturing delays.
- 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.

**Article Link:**

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=490>

**Source Link:** <http://www.ashp.org>

**Nafcillin Sodium**

**June 03, 2015**

**Reason for the Shortage**

- AuroMedics and Fresenius Kabi state the reason for the shortage was increased demand.
- Sagent stated the reason for the shortage is increased demand.
- Sandoz states the reason for the shortage is internal issues.

**Article Link:**

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1136>

**Source Link:** <http://www.ashp.org>

**Midazolam Injections**

**June 03, 2015**

**Reason for the Shortage**

- West-Ward acquired Baxter's midazolam injection products in May, 2011.
- Ben Venue stopped production in its plant in Bedford, Ohio and closed in 2014.

- Hospira has midazolam on shortage due to manufacturing delays and demand exceeding supply due to current market conditions.
- Fresenius Kabi had midazolam on shortage due to increased demand.
- Due to low demand, Akorn is focusing on other medications that are in greater need of supply.
- Sagent has midazolam on shortage due to manufacturing delay.
- Caraco has discontinued all midazolam presentations.
- Caraco discontinued two midazolam presentations in 2014.
- FDA imposed an import ban in mid-2013 on several Wockhardt products including midazolam injection.
- Medicines Company has midazolam on shortage due to short-dated product.
- BD RX introduced midazolam injection in 2014.

**Article Link:**

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=858>

**Source Link:** <http://www.ashp.org>

**Ethiodized Oil**

**June 03, 2015**

**Reason for 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.

**Article Link:**

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

**Source Link:** <http://www.ashp.org>

**Amikacin Injection**

**June 03, 2015**

**Reason for the Shortage**

- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired amikacin injection from Bedford in July 2014. West-Ward is not actively marketing amikacin 250 mg/mL 4 mL vials at this time.
- Teva's product was unavailable due to manufacturing delays.
- Heritage has amikacin injection on shortage due to manufacturing delays.

**Article Link:**

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=501>

**Source Link:** <http://www.ashp.org>

### **Verapamil Injection**

**June 04, 2015**

#### **Reason for the Shortage**

- Hospira has verapamil injection on shortage due to increased demand for the product.
- Hospira is the sole supplier of verapamil injection.

#### **Article Link:**

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=744>

**Source Link:** <http://www.ashp.org>

### **Tamsulosin Hydrochloride Capsules**

**June 05, 2015**

#### **Reason for the Shortage**

- Boehringer Ingelheim could not provide a reason for the shortage.
- Actavis and Zydus state the reason for the shortage is 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.

#### **Article Link:**

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1112>

**Source Link:** <http://www.ashp.org>

### **Sumatriptan Succinate Injection**

**June 05, 2015**

#### **Reason for the Shortage**

- Sagent states the reason for the shortage is increased demand.
- GlaxoSmithKline could not provide a reason for the shortage.
- Pfizer has had Alsuma on shortage since September 2013 due to manufacturing issues.
- Zogenix sold Sumavel DosePro to Endo in 2014.
- Teva has temporarily suspended the production of sumatriptan injection.

#### **Article Link:**

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1085>

**Source Link:** <http://www.ashp.org>

### **Piperacillin Tazobactam Injection**

**June 05, 2015**

#### **Reason for the Shortage**

- Apotex has piperacillin/tazobactam on shortage due to regulatory delays.
- AuroMedics and Sandoz could not provide a reason for the shortage.
- Baxter has Zosyn frozen premixes on allocation due to increased demand.
- Fresenius Kabi has piperacillin/tazobactam on shortage due to increased demand.
- Hospira has piperacillin/tazobactam on shortage due to manufacturing delays.
- 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 September 2015 for the single dose vials and 1st quarter 2017 for the bulk vials.
- WG Critical Care states the reason for the shortage is increased demand.

#### **Article Link:**

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

**Source Link:** <http://www.ashp.org>

### **Pantoprazole Tablets**

**June 05, 2015**

#### **Reason for the Shortage**

- Actavis, Aurobindo, and Mylan could not provide a reason for the shortage.
- Actavis discontinued pantoprazole 20 mg tablets in October 2014.
- Kremers Urban state the shortage is due to increased demand.
- FDA imposed an import ban in mid-2013 on several Wockhardt products including pantoprazole.

#### **Article Link:**

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=979>

**Source Link:** <http://www.ashp.org>

### **L-Cysteine Hydrochloride Injection**

**June 05, 2015**

#### **Reason for the Shortage**

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

- Sandoz has L-cysteine in short supply due to requirements related to complying with good manufacturing practices.

**Article Link:**

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=632>

**Source Link:** <http://www.ashp.org>

**Ciprofloxacin Injection**

**June 05, 2015**

**Reason for the Shortage**

- Claris, Sagent, and Sandoz could not provide a reason for the shortage.
- Hospira has ciprofloxacin injection on back order due to manufacturing delays.

**Article Link:**

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=944>

**Article Link:**

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1101>

**Source Link:** <http://www.ashp.org>

**Vitamin E Aqueous Oral Solution**

**June 08, 2015**

**Reason for the Shortage**

- Hospira is changing manufacturing sites from a 3rd party manufacturer to in-house manufacturing. This has caused a delay in production.

**Article Link:**

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

**Source Link:** <http://www.ashp.org>

**Propranolol Injection**

**June 08, 2015**

**Reason for the Shortage**

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

**Article Link:**

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1091>

**Source Link:** <http://www.ashp.org>

**Posaconazole Oral Suspension**

**June 08, 2015**

**Reason for the Shortage**

- Merck states the shortage is due to manufacturing delays.
- Noxafil delayed-release tablets and intravenous injections are not affected by this shortage.
- Merck is the only supplier of posaconazole oral suspension.

**Article Link:**

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=695>

**Source Link:** <http://www.ashp.org>

**Methylene Blue Injection**

**June 08, 2015**

**Reason for the Shortage**

- Akorn has methylene blue on back order due to manufacturing delays.
- American Regent has methylene blue on back order due to manufacturing delays.

**Article Link:**

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

**Source Link:** <http://www.ashp.org>

**Imipenem Cilastatin Injection**

**June 08, 2015**

**Reason for the Shortage**

- Fresenius has imipenem-cilastatin injection on shortage due to short expiration dating.
- Hospira has imipenem-cilastatin injection on shortage due to manufacturing delays.
- Merck cannot provide a reason for the shortage of Primaxin injection.

**Article Link:**

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1182>

**Source Link:** <http://www.ashp.org>

## Divalproex Sodium Delayed Release Tablets

June 08, 2015

### Reason for the Shortage

- Aurobindo, Dr. Reddy's Laboratories, Lupin, and Qualitest discontinued divalproex sodium delayed release tablets.
- Upsher-Smith had divalproex sodium on long-term back order due to manufacturing delay. Upsher-Smith has transitioned to new NDC numbers.
- Zydus has divalproex sodium delayed-release tablets on allocation due to increased demand.

### Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1124>

**Source Link:** <http://www.ashp.org>

## Chlorothiazide Oral Suspension

June 08, 2015

### Reason for the Shortage

- Valeant cannot provide a reason for the shortage.
- Valeant recently acquired Diuril oral suspension from Salix.

### Article Link:

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

**Source Link:** <http://www.ashp.org>

## Alcohol Dehydrated Injection (Ethanol)

June 08, 2015

### Reason for the Shortage

- American Regent has alcohol dehydrated on back order due to manufacturing delays.
- Hospira and Consolidated Midland discontinued all injectable alcohol dehydrated products.

### Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=778>

**Source Link:** <http://www.ashp.org>

## Acetylcysteine Inhalation Solution

June 08, 2015

### Reason for the Shortage

- American Regent has acetylcysteine oral and inhalation solution on shortage due to manufacturing delays.
- Roxane Labs discontinued acetylcysteine oral and inhalation solution in April 2014.
- Hospira had acetylcysteine oral and inhalation solution on shortage due to manufacturing delay.
- Fresenius Kabi states the reason for the shortage was increased demand.

### Article Link:

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

**Source Link:** <http://www.ashp.org>

## Daunorubicin Hydrochloride Injection

June 09, 2015

### Reason for the Shortage

- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired daunorubicin injection and Cerubidine injection from Bedford in July 2014. West-Ward is not actively marketing daunorubicin injection or Cerubidine injection at this time.
- Teva's daunorubicin injection has a 12 month shelf-life after manufacturing.
- Teva states daunorubicin is on back order due to manufacturing delays.

### Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1007>

**Source Link:** <http://www.ashp.org>

## Carboplatin Solution for Injection

June 09, 2015

### Reason for 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 has carboplatin injection available.
- Sandoz has discontinued carboplatin injection.



- Teva had carboplatin injection on short-term back order due to standard quality inspections.

**Article Link:**

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

**Source Link:** <http://www.ashp.org>

**Azithromycin Injection**

**June 09, 2015**

Reason for the Shortage

- Fresenius Kabi had azithromycin on shortage due to increased demand.
- Hospira has azithromycin injection on shortage due to manufacturing delays.
- Sagent has azithromycin injection on shortage due to manufacturing delays.

**Article Link:**

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=936>

**Source Link:** <http://www.ashp.org>

**Rocuronium Injection**

**June 10, 2015**

Reason for the Shortage

- Merck discontinued Zemuron 10 mL multidose vials in the 3rd Quarter of 2013. Merck discontinued Zemuron 5 mL vials in June 2014.
- Mylan Institutional states the reason for the shortage is increased demand.
- Hospira has rocuronium on shortage due to manufacturing delays.
- Teva has rocuronium on shortage due to manufacturing delays.
- Fresenius Kabi and Sagent cited increased demand as the reason for this shortage.
- Sandoz could not provide a reason for the shortage.
- The Medicines Company launched rocuronium in early 2014.
- X-Gen has rocuronium injection on short-term back order.

**Article Link:**

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=434>

**Source Link:** <http://www.ashp.org>

## Dextrose (50%) Injection

June 10, 2015

### Reason for the Shortage

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

### Article Link:

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

**Source Link:** <http://www.ashp.org>

## Cefotaxime Injection

June 10, 2015

### Reason for the Shortage

- Hospira has discontinued Claforan. Sanofi-Aventis manufactured Claforan for Hospira and is no longer making the product.
- Baxter has Claforan premixed bags on allocation. The company will be discontinuing Claforan 4th quarter 2015.
- West-Ward cannot provide a reason for the shortage.

### Article Link:

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

**Source Link:** <http://www.ashp.org>

## Amino Acid Products

June 10, 2015

### Reason for the Shortage

- Baxter is unable to provide a reason for the shortage.
- BBraun has Plenamine and TrophAmine on allocation due to increased demand.
- Hospira has amino acid products on back order due to manufacturing delays.

### Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=671>

**Source Link:** <http://www.ashp.org>

## Reserpine Oral Tablets

June 11, 2015

### Reason for the Shortage

- Sandoz said the shortage is due to a delay in obtaining raw materials.
- There are no other manufacturers of reserpine tablets.

### Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=975>

**Source Link:** <http://www.ashp.org>

## Pancuronium Injection

June 11, 2015

### Reason for the Shortage

- Teva discontinued their pancuronium presentations in May, 2010.
- Hospira's product is on back order due to manufacturing delays and retesting of raw material. Hospira is the only manufacturer of pancuronium.

### Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=851>

**Source Link:** <http://www.ashp.org>

## Labetalol Injection

June 11, 2015

### Reason for the Shortage

- Hospira has labetalol on shortage due to manufacturing delays and increased demand.
- Sagent suspended production on labetalol 5 mg/mL 20 mL vials (NDC 25021-0300-20) in July 2013 and 40 mL vials in February 2014 (NDC 25021-0300-40) and the company has no estimated release date for further production.
- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired several products from Bedford Laboratories in July 2014 including labetalol injection. West-Ward is not actively marketing labetalol injection.

### Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=397>

**Source Link:** <http://www.ashp.org>

### Fenoldopam Mesylate Injection

June 11, 2015

#### Reason for the Shortage

- Hospira has Corlopam vials on shortage due to manufacturing delays.

#### Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1031>

**Source Link:** <http://www.ashp.org>

### Droperidol Injection

June 11, 2015

#### Reason for the Shortage

- American Regent has droperidol injection on unavailable due to manufacturing delays.
- Hospira has droperidol unavailable due to shortage of raw material.

#### Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=818>

**Source Link:** <http://www.ashp.org>

### Dexpanthenol Injection

June 11, 2015

#### Reason for the Shortage

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

#### Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1103>

**Source Link:** <http://www.ashp.org>

### Ceftazidime Injection

June 11, 2015

#### Reason for the Shortage

- Covis had Fortaz premixed bags on shortage due to increased demand.
- Hospira has Tazicef on shortage due to increased demand.
- Sagent has ceftazidime injection on shortage due to manufacturing delays.

**Article Link:**

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

**Source Link:** <http://www.ashp.org>

**Cefazolin Injection**

**June 11, 2015**

**Reason for the Shortage**

- B Braun has cefazolin on shortage due to increased demand.
- Fresenius Kabi has cefazolin on shortage due to increased demand.
- WG Critical Care has cefazolin on shortage due to increased demand. WG Critical Care discontinued cefazolin 20 gram to focus on other strengths.
- Sandoz has cefazolin on shortage due to manufacturing delays.
- Hospira has cefazolin on shortage due to increased demand.
- Sagent has cefazolin on shortage due to increased demand.

**Article Link:**

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=987>

**Source Link:** <http://www.ashp.org>

**Black Widow Antivenin (Latrodectus Mactans)**

**June 11, 2015**

**Reason for the Shortage**

- Merck has low inventory of Antivenin Latrodectus Mactans.

**Article Link:**

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=670>

**Source Link:** <http://www.ashp.org>

**Benztropine Injection**

**June 11, 2015**

**Reason for the Shortage**

- American Regent has benztropine injection on back order due to manufacturing delays.
- Fresenius Kabi recalled benztropine injection due to potential for glass particles in the vials. The product is on long-term back order.
- Nexus divested benztropine injection to Fresenius Kabi in 2012.

**Article Link:**

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

**Source Link:** <http://www.ashp.org>

**Azathioprine Injection**

**June 11, 2015**

**Reason for the Shortage**

- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired azathioprine injection from Bedford in July 2014. West-Ward is not actively marketing azathioprine injection.
- There are no other manufacturers of azathioprine injection.
- The oral presentations are not affected by this shortage.

**Article Link:**

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=935>

**Source Link:** <http://www.ashp.org>

**Zinc Injection**

**June 12, 2015**

**Reason for the Shortage**

- Hospira states the shortage of zinc chloride injection was due to manufacturing delays.
- American Regent states the shortage of zinc sulfate injection is due to manufacturing delays.

**Article Link:**

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=777>

**Source Link:** <http://www.ashp.org>

**Furosemide Injection**

**June 12, 2015**

**Reason for the Shortage**

- Fresenius Kabi has furosemide injection on shortage due to increased demand for the product.
- American Regent has furosemide injection on shortage due to manufacturing delays.
- Hospira has furosemide injection available.
- Wockhardt has discontinued all furosemide injection presentations.
- Claris could not provide a reason for the shortage.

**Article Link:**

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=636>

**Source Link:** <http://www.ashp.org>

**Trace Elements Injection**

**June 15, 2015**

**Reason for the Shortage**

- American Regent has trace element injection on back order due to manufacturing delays.
- American Regent is the sole supplier of FDA-approved combined trace elements.
- In cooperation with FDA, Fresenius Kabi USA is providing Addamel N (adult trace element injection) and Peditrace (pediatric trace element injection) to the US market to help alleviate the shortage. Addamel N and Peditrace are manufactured in an FDA-approved facility in Norway by Fresenius Kabi AG, the parent company of Fresenius Kabi, USA.

**Article Link:**

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=785>

**Source Link:** <http://www.ashp.org>

**Torsemide Injection**

**June 15, 2015**

**Reason for the Shortage**

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

**Article Link:**

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=344>

**Source Link:** <http://www.ashp.org>

**Tobramycin Injection**

**June 15, 2015**

**Reason for the Shortage**

- Teva has tobramycin solution for injection on shortage due to manufacturing delays.
- Hospira has tobramycin on shortage due to manufacturing delays.

- Fresenius Kabi has tobramycin solution for injection on shortage due to increased demand.
- Mylan Institutional could not provide a reason for the shortage.

**Article Link:**

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

**Source Link:** <http://www.ashp.org>

**Synthetic Conjugated Estrogen**

**June 15, 2015**

**Reason for the Shortage**

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

**Article Link:**

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1087>

**Source Link:** <http://www.ashp.org>

**Sodium Bicarbonate Injection**

**June 15, 2015**

**Reason for the Shortage**

- Hospira has sodium bicarbonate on back order due to increased demand.
- Hospira is the sole supplier of the 4.2% 10 mL syringes used in pediatric patients.
- Amphastar had sodium bicarbonate on back order due to increased demand.

**Article Link:**

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=788>

**Source Link:** <http://www.ashp.org>

**Nitroglycerin Injection**

**June 15, 2015**

**Reason for the Shortage**

- American Regent has nitroglycerin vials on back order due to manufacturing delays.
- Hospira discontinued nitroglycerin injection in early 2015.2
- Baxter had nitroglycerin premixes on shortage due to a raw material supply issue.
- Baxter had nitroglycerin premixes on shortage due to low supplies.



**Article Link:**

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=786>

**Source Link:** <http://www.ashp.org>

**Methylprednisolone Acetate Injection**

**June 15, 2015**

**Reason for the Shortage**

- Sandoz and Teva could not provide a reason for the shortage.
- Pfizer has Depo-Medrol injection available and is supplying the market.

**Article Link:**

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=923>

**Source Link:** <http://www.ashp.org>

**Methylphenidate Hydrochloride Extended Release Oral Presentations**

**June 15, 2015**

**Reason for the Shortage**

- Actavis states the shortage of methylphenidate is due to increased demand. Actavis estimates a shortage of methylphenidate ER tablets will begin in December 2014 and last through 2nd quarter 2015.
- Janssen states the shortage of Concerta is due to increased demand. Janssen estimates a shortage of Concerta will begin in December 2014 and last through 2nd quarter 2015.
- Kremers Urban has Methylphenidate CD on allocation due to increased demand.
- Novartis discontinued Ritalin SR in October 2014.
- Teva introduced generic methylphenidate extended release capsules (CD) in late-September 2012, and these capsules are AB-rated to Metadate CD capsules.
- UCB states methylphenidate ER tablets were on shortage due to supply and demand.

**Article Link:**

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1166>

**Source Link:** <http://www.ashp.org>

**Flumazenil Injection**

**June 15, 2015**

**Reason for the Shortage**

- Fresenius Kabi has flumazenil on shortage due to short-term manufacturing delays.
- Sandoz and Mylan Institutional cannot provide a reason for the shortage.

**Article Link:**

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

**Source Link:** <http://www.ashp.org>

**Famotidine Injection**

**June 15, 2015**

**Reason for 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.
- Fresenius Kabi has famotidine injection on shortage due to increased demand.
- Baxter has famotidine premixed bags available.

**Article Link:**

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=810>

**Source Link:** <http://www.ashp.org>

**Etomidate Injection**

**June 15, 2015**

**Reason for the Shortage**

- American Regent has etomidate injection on shortage due to manufacturing delays.
- Ben Venue stopped production in its plant in Bedford, Ohio and closed in July 2014.
- Hospira has Amidate injection on shortage due to increased demand.
- Par Sterile Products discontinued etomidate in early 2015.

**Article Link:**

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

**Source Link:** <http://www.ashp.org>

**Deferoxamine Mesylate Injection**

**June 15, 2015**

**Reason for the Shortage**

- Fresenius Kabi states the shortage was due to increased demand.
- Hospira has deferoxamine on shortage due to increased demand.
- Teva discontinued all deferoxamine presentations in 2013.

- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired deferoxamine injection from Bedford in July 2014. West-Ward is not actively marketing deferoxamine injection at this time.
- Watson discontinued all deferoxamine presentations.

**Article Link:**

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1008>

**Source Link:** <http://www.ashp.org>

### Calcium Gluconate Injection

June 15, 2015

**Reason for the Shortage**

- American Regent has calcium gluconate on shortage due to manufacturing delays.
- Fresenius Kabi has replaced calcium gluconate glass vials with plastic vials.
- 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.

**Article Link:**

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

**Source Link:** <http://www.ashp.org>

### Ampicillin Sulbactam

June 15, 2015

**Reason for the Shortage**

- AuroMedics Pharma launched new product in mid-June, 2012.
- Hospira states that ampicillin sulbactam vials are on back order due to manufacturing delay.
- Mylan Institutional discontinued ampicillin sulbactam injection in late 2013.
- 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.
- WG Critical Care launched ampicillin sulbactam 1.5 gram vials in March 2014.
- West-Ward acquired several Baxter products in early 2011.

**Article Link:**

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

**Source Link:** <http://www.ashp.org>

### Multiple Vitamins for Infusion

June 16, 2015

#### Reason for the Shortage

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

#### Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=831>

**Source Link:** <http://www.ashp.org>

### Lactated Ringer's Irrigation

June 16, 2015

#### Reason for the Shortage:

- Baxter has lactated ringer's on shortage due to manufacturing delays
- Bbrain has lacted ringer's irrigation on shortage due to increased demand
- Hospira has lactated ringer's on shortage due ot increase demand

#### Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1119>

**Source Link:** <http://www.ashp.org>

### Epinephrine Injection

June 16, 2015

#### Reason for 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 infection in 2014 and the company launched product in February 2015
- Hospira has epinephrine syringes on shortage due to increased demand

#### Article Link:

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

**Source Link:** <http://www.ashp.org>

## Doxorubicin Liposomal Injection

June 16, 2015

### Reason for the Shortage

- Janssen Products, LP states the shortage is due to manufacturing issues. Janssen Products, LP has updates with information about the shortage on the Doxil website that is updated regularly
- FDA approved a new manufacturer of Doxil in January 2015
- Ben Venue has stopped production in its plant in Bedford, Ohio and closed in 2014
- Caraco launched generic doxorubicin liposomal injection in mid-March 2013 and can supply market with their presentations

### Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=806>

**Source Link:** <http://www.ashp.org>

## Atropine Sulfate Ophthalmic Solution

June 16, 2015

### Reason for the Shortage

- Alcon has Isopto Atropine only available through whole salers and not available for direct order
- Akorn received FDA approval for atropine sulfate 1% ophthalmic solution in July 2014; this new product launched in January 2015. All other atropine sulfate ophthalmic solution products are unapproved products
- Sandoz could not provide a reason for the shortage
- Valeant discontinued their atropine sulfate 1% ophthalmic solution products in 2015

### Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1146>

**Source Link:** <http://www.ashp.org>

## Atenolol Tablets

June 16, 2015

### Reason for the Shortage

- AstraZeneca divested Tenormin to Almatica in January 2015.
- Almatica has new NDC numbers for Tenormin tablets.
- Avkare and Mylan Pharmaceuticals could not provide a reason for the shortage.
- Pack Pharmaceuticals discontinued atenolol tablets in October 2014.
- Ranbaxy has atenolol tablets on shortage due to manufacturing delays.

- Zydus has atenolol tablets on allocation due to increased demand.
- Aurobindo and Caraco have discontinued atenolol tablets.

**Article Link:**

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1127>

**Source Link:** <http://www.ashp.org>

**Tacrolimus Capsules**

**June 17, 2015**

**Reason for the Shortage**

- Novartis discontinued all Hecoria presentations in February 2015.
- Mylan discontinued the 500 count presentations in early 2015.
- Mylan and Kremers Urban could not provide a reason for the shortage.
- Sandoz states the reason for the shortage is manufacturing delay.

**Article Link:**

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1149>

**Source Link:** <http://www.ashp.org>

**Sodium Chloride 0.9% Injection Bags**

**June 17, 2015**

**Reason for the Shortage**

- Baxter has 0.9% sodium chloride on shortage due to increased demand
- BBraun had 0.9% sodium chloride on allocation due to increased demand
- Hospira cites increased demand as the reason for the shortage
- In cooperation with the FDA, Fresenius Kabi is providing 0.9% sodium chloride to the US market to help alleviate the national shortage. This 0.9% sodium chloride is manufactured in an FDA-approved facility in Norway by Fresenius Kabi AG. There will be presentations available with Australian/English label and the package insert is the same for all imported presentations
- In cooperation with the FDA, Baxter is providing 0.9% sodium chloride to the US market to help alleviate the national shortage. This 0.9% sodium chloride in Viaflo containers is manufactured in an FDA-approved facility in Spain by Baxter

**Article Link:**

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

**Source Link:** <http://www.ashp.org>

### **Milrinone Injection**

**June 17, 2015**

#### **Reason for the Shortage**

- Fresenius Kabi states the reason for the shortage is increased demand for the product
- Hospira has milrinone injection on shortage due to increased demand
- West-Ward states the shortage is due to manufacturing delay

#### **Article Link:**

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=741>

**Source Link:** <http://www.ashp.org>

### **Methotrexate Injection**

**June 17, 2015**

#### **Reason for the Shortage**

- Mylan Institutional cannot provide a reason for the shortage
- Sandoz discontinued methotrexate 2 mL and 10 mL
- West-Ward Pharmaceutical's parent company, Hikma Pharmaceuticals, acquired several products from Bedford Laboratories in July 2014 including methotrexate injection. West-Ward is not actively marketing methotrexate injection
- Teva has methotrexate on short-term back order for standard quality control

**Article Link:** <http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=26>

**Source Link:** <http://www.ashp.org>

### **Estradiol Valerate Injection**

**June 17, 2015**

#### **Reason for the Shortage**

- Par states the reason for the shortage is manufacturing delay
- Perrigo states the reason for the shortage is manufacturing issue

#### **Article Link:**

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1186>

**Source Link:** <http://www.ashp.org>

## Cefepime Injection

June 17, 2015

### Reason for the Shortage

- Apotex could not provide a reason for the shortage
- Fresenius Kabi has cefepime injection on shortage due to manufacturing delays
- Sagent has cefepime injection on shortage due to increase demand
- Sandox cannot provide a reason for the shortage
- Hospira has Maxipime on shortage due to increased demand

### Article Link:

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

**Source Link:** <http://www.ashp.org>

## Carbidopa and Levodopa Extended-Release Tablets

June 17, 2015

### Reason for the Shortage

- Caraco could not provide a reason for the shortage
- Merck could not provide a reason for the shortage

### Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1181>

**Source Link:** <http://www.ashp.org>

## Calcium Chloride Injection

June 17, 2015

### Reason for the 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 increased demand
- Mylan Institutional cannot provide a reason for the shortage

### Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=941>

**Source Link:** <http://www.ashp.org>



## BCG Vaccine Live Intravesical

June 17, 2015

### Reason for the Shortage

- Sanofi Pasteur states the reason for the shortage is manufacturing delay
- Merck states the reason for the shortage is manufacturing delay
- Merck states Tice BCG vaccine percutaneous for tuberculosis (Merck, NDC 00052-0603-02) is also affected because this product is manufactured at the same facility

### Article Link:

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

**Source Link:** <http://www.ashp.org>

## Dibucaine Ointment

June 18, 2015

### Reason for the Shortage

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

### Article Link:

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

**Source Link:** <http://www.ashp.org>

## Azathioprine Tablets

June 18, 2015

### Reason for the Shortage

- Roxane discontinued azathioprine tablets in mid-January 2015 due to problems obtaining active ingredient
- Valeant acquired Salix Pharmaceuticals in April 2015
- Mylan could not provide a reason for the shortage
- Prometheus Laboratories states the reason for the shortage was increased demand

### Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1123>

**Source Link:** <http://www.ashp.org>

### Phosphate 300 mg/30 mg Tablets

June 18, 2015

#### Reason for the Shortage

- Mallinckrodt states the shortage is due a variety of market conditions.
- Amneal, Aurobindo, Mylan, and Teva could not provide a reason for the shortage.
- Qualitest will not provide shortage information for any of their products because they consider the information to be proprietary.

#### Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1152>

**Source link:** <http://www.ashp.org>

### Heparin Premixed Bags

June 18, 2015

#### Reason for the Shortage

- Baxter and Bbrain had product on allocation due to increased demand
- Hospira states the reason for the shortage is manufacturing delays

#### Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1169>

**Source link:** <http://www.ashp.org>

### Hydroxyzine Hydrochloride Injection

June 19, 2015

#### Reason for the Shortage

- American Regent had hydroxyzine injection on shortage due to manufacturing delays
- American Regent is the sole supplier of hydroxyzine injection

#### Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1185>

**Source link:** <http://www.ashp.org>

## Atracurium Injection

June 22, 2015

### Reason for the Shortage

- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired several products from Bedford Laboratories in July 2014 including atracurium injection. West-Ward is not actively marketing atracurium.
- Hospira has atracurium available.
- Sagent has atracurium on shortage due to product recall.

### Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=872>

**Source link:** <http://www.ashp.org>

## Benzonatate Capsules

June 22, 2015

### Reason for the Shortage

- Amneal and Ascend Laboratories cannot provide a reason for the shortage.
- Caraco discontinued benzonatate capsules in mid-2015.
- Zydus states the reason for the shortage is manufacturing delay.
- Pfizer has Tessalon Perles on shortage due to supply and demand issues.

### Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1155>

**Source link:** <http://www.ashp.org>

## Caffeine Citrate Injection and Oral Solution

June 22, 2015

### Reason for the Shortage

- American Regent has caffeine citrate on shortage due to manufacturing delays.
- Caraco discontinued caffeine citrate oral solution in mid-2015.
- Exela Pharma Sciences launched caffeine citrate oral solution and intravenous injection in mid-2015.
- Paddock discontinued caffeine citrate injection and oral solution in May 2014.
- Sagent states the reason for the shortage is manufacturing delays.
- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired Cafcit from Bedford in July 2014. West-Ward is actively marketing Cafcit injection.

**Article link:**

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=862>

**Source link:** <http://www.ashp.org>

**Ceftriaxone Sodium Injection**

**June 22, 2015**

**Reason for the Shortage**

- Ben Venue stopped production in its plant in Bedford, Ohio and closed in July 2014.
- Fresenius Kabi states the reason for the shortage is increased demand.
- Hospira states the reason for the shortage is manufacturing delay.
- Sagent states the reason for the shortage is increased demand.
- Sandoz could not provide a reason for the shortage.
- WG Critical Care states the reason for the shortage is increased demand.

**Article link:**

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1101>

**Source link:** <http://www.ashp.org>

**Desmopressin Injection**

**June 22, 2015**

**Reason for the Shortage**

- Teva and Hospira have desmopressin injection on shortage due to manufacturing delays.
- Ferring acquired marketing rights of DDAVP from Sanofi in October 2014.

**Article link:**

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1010>

**Source link:** <http://www.ashp.org>

**Leucovorin Calcium Injection**

**June 22, 2015**

**Reason for the Shortage**

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

**Article link:**

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

**Source link:** <http://www.ashp.org>

**Leuprolide Acetate 14-Day Kit**

**June 22, 2015**

**Reason for the Shortage**

- Caraco has a new NDC number for the leuprolide injection.
- Teva states the shortage is due to manufacturing delays.

**Article link:**

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=737>

**Source link:** <http://www.ashp.org>

**Levetiracetam Injection**

**June 22, 2015**

**Reason for the Shortage**

- American Regent states the reason for the shortage is manufacturing delay.
- Caraco cannot provide a reason for the shortage.
- Fresenius states the reason for the shortage is manufacturing delay.
- Hospira states the reason for the shortage is increased demand.
- Sagent states the reason for the shortage is increased demand.
- X-Gen states the reason for the shortage is change in manufacturing site.

**Article link:**

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1183>

**Source link:** <http://www.ashp.org>

**Lidocaine Hydrochloride Oral Topical Solution (Viscous) 2%**

**June 22, 2015**

**Reason for the Shortage**

- Akorn could not provide a reason for the shortage.
- Roxane states the shortage was due to increased demand.
- Qualitest will not provide shortage information for any of their products because they consider the information to be proprietary.

**Article link:**

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1171>

**Source link:** <http://www.ashp.org>

**Lidocaine Topical 4% Solution**

**June 22, 2015**

**Reason for the Shortage**

- Hospira discontinued LTA Syringes kits on August 5, 2014 due to a business decision.
- Amphastar had Laryng-O-Jets on shortage due to increased demand.

**Article link:**

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1128>

**Source link:** <http://www.ashp.org>

\* Please refer to ASHP website for more information

## NEW DRUGS COMING TO MARKET

PRODUCT	MFR	ROUTE	INDICATION	PHARMACOLOGY	MARKET RELEASE
LY2963016	Boehringer Ingelheim/ Eli Lilly	INJ (SC)	Type I and II diabetes	Novel version of insulin glargine (biosimilar to Lantus)	NDA was filed 12-2013 under 505(b)(2) application; received tentative approval 8/2014; patent infringement lawsuit may delay launch beyond 2/2015
Sonidegib (LDE-225)	Novartis	PO	Basal cell carcinoma	Smoothend (Smo) antagonist; Hedgehog (Hh) signaling pathway inhibitor	NDA filed 10/2014
Evolocumab (AMG-145)	Amgen	INJ (SC)	Hyper-cholesterolemia	Fully human antibody that targets PCSK9; dosed every 2 or every 4 weeks in studies	NDA filed 8/2014; FDA action date 8/2015
Brexpiprazole	Otsuka	PO	Depression, ADHD, schizophrenia	D2 dopamine partial agonist	NDA filed 7/2014; FDA action date 7/2015
Aripiprazole lauroxil	Alkermes	INJ	Schizophrenia	Long-acting atypical antipsychotic dosed every 2 months	NDA filed 8/2014; FDA action date 8/2015
Rolapitant	TESARO/ OPKO Health	PO	Chemotherapy induced nausea and vomiting (prevention)	Neurokinin 1 receptor antagonists	NDA filed 9/2014
Drisapersen	Prosensa	INJ (SC)	Duchenne Muscular Dystrophy	Antisense nucleotide that induced specific skipping of exon 51 during splicing	Phase III; FDA breakthrough therapy designation granted 6/2013;

PRODUCT	MFR	ROUTE	INDICATION	PHARMACOLOGY	MARKET RELEASE
					Rolling NDA initiated 10/2014
Mepolizumab (Bosatria)	GSK	INJ (IV,SC)	Asthma, nasal polyposis	Humanized monoclonal antibody against human interleukin-5 (IL-5)	BLA filed 11/2014 for treatment of asthma  Pdufa date 11/4/2015
Ivacaftor/lumacaftor	Vertex	PO	Cystic fibrosis	Fixed-dose combination of lumacaftor and ivacaftor (transmembrane conductance regulator stimulants)	FDA Breakthrough Therapy Designation 1/2013; NDA filed 11/2014 pdufa date of 7/5/2015
Asfotase	Enobia Pharma	INJ (SC)	Hypophosphatasia	Recombinant fusion protein that includes the catalytic domain of human tissue non-specific alkaline phosphate (TNSALP)	FDA breakthrough therapy designation 5/2013; rolling BLA initiated 4/2014
Patiromer	Relypsa	PO	Hyperkalemia	Non-absorbed oral polymeric compound known as patiromer, a potassium binder	NDA filed 10/2014
CEP-33237	Teva	PO	Moderate to severe pain	Hydrocodone extended release with abuse deterrent properties; dosed once daily	Phase III; Rolling NDA initiated 10/2014
MNK-155	Mallinkrodt	PO	Moderate to moderately severe acute pain	Hydrocodone and acetaminophen extended release	NDA submitted 5/2014
Alirocumab (Praluent)	Regeneron/Sanofi	INJ (SC)	Hypercholesterolemia	Fully human antibody that targets PCSK9	BLA accepted 1/2015, PDUFA 7/2015



PRODUCT	MFR	ROUTE	INDICATION	PHARMACOLOGY	MARKET RELEASE
Trabectedin	Janssen	INJ (IV)	Soft tissue sarcoma	Activates caspase-8-dependent cascade of apoptosis, sensitizes cancer cells to FAS-mediated cell death, interacts with minor groove of DNA double helix to cause lethal DNA strand breaks	NDA 11/2014, PDUFA 11/2015
Cobimetinib	Genentech	PO	BRAF mutation melanoma	MEK inhibitor that targets BRAF mutation	NDA submitted 12/2014, PDUFA 8/2015
Sebelipase alfa (Kanuma)	Synageva/BioPharma	INJ (IV)	Lysosomal Acid Lipase Deficiency	Acts as a replace to the enzyme Lysosomal Acid Lipase	PDUFA 9/2015
Valsartan/Sacubitril (Entresto)	Novartis	PO	Heart Failure	ARB/ Neprilysin inhibitor	Granted priority review 2/2015 PDUFA date 8/2015