



February 2015*

Drug Information Update

DRUG INFORMATION UPDATE

Table of Contents

NEW GENERICS TO MARKET	2
NEW DRUG ENTITIES	3
NEW INDICATIONS (EXISTING DRUGS)	7
FDA NEWS/BULLETINS/ADVISORIES/SAFETY ALERTS	8
STUDIES and RECENT TOPICS	13
RECALLS	20
CURRENT DRUG SHORTAGES	27
NEW DRUGS COMING TO MARKET	73

NEW GENERICS TO MARKET

GENERIC DRUG NAME	STRENGTH & DOSAGE FORM	GENERIC MANUFACTURER	BRAND NAME	APPROVAL DATE
COLCHICINE	0.6MG TABLET	PRASCO LABS	COLCRYS	01/12/15
COLCHICINE	0.6MG CAPSULE	WEST-WARD, INC.	MITIGARE	01/12/15
LAMOTRIGINE	50 MG TAB RAP DIS	GLOBAL PHARM	LAMICTAL ODT	01/26/15
LAMOTRIGINE	200 MG TAB RAP DIS	GLOBAL PHARM	LAMICTAL ODT	01/26/15
LAMOTRIGINE	100 MG TAB RAP DIS	GLOBAL PHARM	LAMICTAL ODT	01/26/15
LAMOTRIGINE	25 MG TAB RAP DIS	GLOBAL PHARM	LAMICTAL ODT	01/26/15
DEXMETHYLPHENIDATE HCL	10 MG CPBP 50-50	TEVA USA	FOCALIN XR	02/03/15
DEXMETHYLPHENIDATE HCL	10 MG CPBP 50-50	SANDOZ	FOCALIN XR	02/04/15
PRAMIPEXOLE DI-HCL	1.5 MG TAB ER 24H	PAR PHARM	MIRAPEX ER	02/10/15
PRAMIPEXOLE DI-HCL	0.75 MG TAB ER 24H	PAR PHARM	MIRAPEX ER	02/10/15
ESOMEPRAZOLE MAGNESIUM	40 MG CAPSULE DR	TEVA USA	NEXIUM	02/17/15
ESOMEPRAZOLE MAGNESIUM	20 MG CAPSULE DR	TEVA USA	NEXIUM	02/17/15
NEOSTIGMINE METHYLSULFATE	0.5 MG/ML VIAL	APP PHARM	BLOXIVERZ	02/18/15
NEOSTIGMINE METHYLSULFATE	1 MG/ML VIAL	APP PHARM	BLOXIVERZ	02/18/15

NEW DRUG ENTITIES

DESCRIPTION	BRAND NAME	GENERIC NAME	STRENGTH	NOTES
NARCOTIC ANTITUSSIVE- EXPECTORANT COMBINATION	OBREDON	GUAIFENESIN/HYDROCO DONE	200-2.5/5	New Combination
DIETARY SUPPLEMENT, MISCELLANEOUS	CERENX	CITICOLINE SODIUM	500 MG	New Entity
ANALGESICS, NARCOTICS	OXYCONTIN	OXYCODONE HCL	10 MG	NDC Reclassification
ANALGESICS, NARCOTICS	OXYCONTIN	OXYCODONE HCL	20 MG	NDC Reclassification
ANALGESICS, NARCOTICS	OXYCONTIN	OXYCODONE HCL	15 MG	NDC Reclassification
ANALGESICS, NARCOTICS	OXYCONTIN	OXYCODONE HCL	30 MG	NDC Reclassification
ANALGESICS, NARCOTICS	OXYCONTIN	OXYCODONE HCL	40 MG	NDC Reclassification
ANALGESICS, NARCOTICS	OXYCONTIN	OXYCODONE HCL	60 MG	NDC Reclassification
ANALGESICS, NARCOTICS	OXYCONTIN	OXYCODONE HCL	80 MG	NDC Reclassification
ANALGESICS, NARCOTICS	EMBEDA	MORPHINE SULFATE/NALTREXONE	20MG- 0.8MG	New Formulation
ANALGESICS, NARCOTICS	EMBEDA	MORPHINE SULFATE/NALTREXONE	30MG- 1.2MG	New Formulation
ANALGESICS, NARCOTICS	EMBEDA	MORPHINE SULFATE/NALTREXONE	50 MG-2 MG	New Formulation
ANALGESICS, NARCOTICS	EMBEDA	MORPHINE SULFATE/NALTREXONE	60MG- 2.4MG	New Formulation
ANALGESICS, NARCOTICS	EMBEDA	MORPHINE SULFATE/NALTREXONE	80MG- 3.2MG	New Formulation
ANALGESICS, NARCOTICS	EMBEDA	MORPHINE SULFATE/NALTREXONE	100MG- 4MG	New Formulation
ANTIPSYCHOTICS, ATYP, D2 PARTIAL AGONIST/5HT MIXED	ABILIFY MAINTENA	ARIPIRAZOLE	300 MG	New Dosage Form
ANTIPSYCHOTICS, ATYP, D2 PARTIAL AGONIST/5HT MIXED	ABILIFY MAINTENA	ARIPIRAZOLE	400 MG	New Dosage Form
ADRENERGICS, AROMATIC, NON- CATECHOLAMINE	VYVANSE	LISDEXAMFETAMINE DIMESYLATE	10 MG	New Strength

DESCRIPTION	BRAND NAME	GENERIC NAME	STRENGTH	NOTES
DIRECT FACTOR XA INHIBITORS	SAVAYSA	EDOXABAN TOSYLATE	15 MG	New Entity
DIRECT FACTOR XA INHIBITORS	SAVAYSA	EDOXABAN TOSYLATE	30 MG	New Entity
DIRECT FACTOR XA INHIBITORS	SAVAYSA	EDOXABAN TOSYLATE	60 MG	New Entity
IRON REPLACEMENT	FERIVA FA	IRON/FA#1/C/B12/BIOT/COPPR/DSS	110 MG-1MG	New Combination
ANTIPARKINSONISM DRUGS,OTHER	RYTARY	CARBIDOPA/LEVODOPA	23.75-95MG	New Strength and Dosage Form
ANTIPARKINSONISM DRUGS,OTHER	RYTARY	CARBIDOPA/LEVODOPA	36.25-145	New Strength and Dosage Form
ANTIPARKINSONISM DRUGS,OTHER	RYTARY	CARBIDOPA/LEVODOPA	48.75-195	New Strength and Dosage Form
ANTIPARKINSONISM DRUGS,OTHER	RYTARY	CARBIDOPA/LEVODOPA	61.25-245	New Strength and Dosage Form
LEUKOCYTE (WBC) STIMULANTS	NEULASTA	PEGFILGRASTIM	6MG/0.6ML	New Dosage Form
HYPERPARATHYROID TX AGENTS - VITAMIN D ANALOG-TYPE	PARICALCITOL	PARICALCITOL	2 MCG/ML	New Route
TOPICAL LOCAL ANESTHETICS	ADAZIN	LIDOCAINE/BENZOCAIN/ME-SAL/CAP	2 %-2%-10%	New Combination
TOPICAL LOCAL ANESTHETICS	SCAR	LIDOCAINE/ALLANTOIN/PETROLATUM	5 %-2%-30%	New Strength
ANTI-INFLAMMATORY, PHOSPHODIESTERASE-4(PDE4) INHIB.	OTEZLA	APREMILAST	10-20-30MG	New Strength and Dosage Form
NUTRITIONAL TX, PHENYLKETONURIA (PKU) FORMULATIONS	PKU PERIFLEX JUNIOR PLUS	NUT. TX FOR PKU WITH IRON #55	28 G-377	New Combination
BETA-ADRENERGIC BLOCKING AGENTS	SOTYLIZE	SOTALOL HCL	5 MG/ML	New Strength and Dosage Form
NUTRITIONAL THERAPY, MED COND SPECIAL FORMULATION	NOVASOURCE RENAL 2 CAL	NUT.TX. IMPAIRED RENAL FXN,SOY	0.09G-2/ML	New Combination
SOMATOSTATIC AGENTS	SIGNIFOR LAR	PASIREOTIDE PAMOATE	20 MG	New Salt Form/Route
SOMATOSTATIC AGENTS	SIGNIFOR LAR	PASIREOTIDE PAMOATE	40 MG	New Salt Form/Route

DESCRIPTION	BRAND NAME	GENERIC NAME	STRENGTH	NOTES
SOMATOSTATIC AGENTS	SIGNIFOR LAR	PASIREOTIDE PAMOATE	60 MG	New Salt Form/Route
EYE ANTIHISTAMINES	PAZEO	OLOPATADINE HCL	0.70%	New Strength
ANTINEOPLASTIC SYSTEMIC ENZYME INHIBITORS	LENVIMA	LENVATINIB MESYLATE	24 MG/DAY	New Entity
ANTINEOPLASTIC SYSTEMIC ENZYME INHIBITORS	LENVIMA	LENVATINIB MESYLATE	14 MG/DAY	New Entity
ANTINEOPLASTIC SYSTEMIC ENZYME INHIBITORS	LENVIMA	LENVATINIB MESYLATE	10 MG/DAY	New Entity
ANTINEOPLASTIC SYSTEMIC ENZYME INHIBITORS	LENVIMA	LENVATINIB MESYLATE	20 MG/DAY	New Entity
ANTIOXIDANT MULTIVITAMIN COMBINATIONS	OCUVEL	FA/VIT C/E/ZINC/COPPER/LUT/Z EA	0.5-250 MG	New Combination
ADRENERGICS, AROMATIC, NON-CATECHOLAMINE	EVEKEO	AMPHETAMINE SULFATE	10 MG	New Entity
ADRENERGICS, AROMATIC, NON-CATECHOLAMINE	EVEKEO	AMPHETAMINE SULFATE	5 MG	New Entity
HEMORRHOIDAL PREP, ANTI-INFLAM STEROID/LOCAL ANESTH	LIDOCAINE-HYDROCORTISONE	HYDROCORTISONE AC/LIDOCAINE	0.5 %-3 %	New Strength
TOPICAL LOCAL ANESTHETICS	PAIN RELIEF	LIDOCAINE HCL/MENTHOL	5 %-1 %	New Strength
ANTINEOPLASTIC, ANTI-PROGRAMMED DEATH-1 (PD-1) MAB	KEYTRUDA	PEMBROLIZUMAB	100 MG/4ML	New Strength
ANTIVIRALS, HIV-1 INTEGRASE STRAND TRANSFER INHIBTR	VITEKTA	ELVITEGRAVIR	85 MG	New Entity
ANTIVIRALS, HIV-1 INTEGRASE STRAND TRANSFER INHIBTR	VITEKTA	ELVITEGRAVIR	150 MG	New Entity
GRAM NEGATIVE COCCI VACCINES	BEXSERO	MENINGOCOCCAL B VACC, 4-COMP/PF	50-50/0.5	New Entity
ANTIHYPERTENSIVE, SGLT-2 & DPP-4 INHIBITOR COMB.	GLYXAMBI	EMPAGLIFLOZIN/LINAGLIPTIN	10 MG-5 MG	New Entity

DESCRIPTION	BRAND NAME	GENERIC NAME	STRENGTH	NOTES
ANTIHYPERGLYCEMIC, SGLT-2 & DPP-4 INHIBITOR COMB.	GLYXAMBI	EMPAGLIFLOZIN/LINAGLIPTIN	25 MG-5 MG	New Entity
SEDATIVE-HYPNOTICS, NON-BARBITURATE	PRECEDEX	DEXMEDETOMIDINE IN 0.9 % NAACL	80MCG/20 ML	New Strength and Dosage Form
NARCOTIC WITHDRAWAL THERAPY AGENTS	ZUBSOLV	BUPRENORPHINE HCL/NALOXONE HCL	8.6-2.1 MG	New Strength
MU-OPIOID RECEPTOR ANTAGONISTS, PERIPHERALLY-ACTING	MOVANTIK	NALOXEGOL OXALATE	12.5 MG	New Entity
MU-OPIOID RECEPTOR ANTAGONISTS, PERIPHERALLY-ACTING	MOVANTIK	NALOXEGOL OXALATE	25 MG	New Entity
ANTIPARKINSONISM DRUGS, OTHER	DUOPA	CARBIDOPA/LEVODOPA	4.63-20/ML	New Route and Dosage Form
ANTIPSORIATIC AGENTS, SYSTEMIC	COSENTYX	SECUKINUMAB	150 MG/ML	New Entity
ANTIPSORIATIC AGENTS, SYSTEMIC	COSENTYX	SECUKINUMAB	150 MG/ML	New Entity
ANTINEOPLASTIC SYSTEMIC ENZYME INHIBITORS	IBRANCE	PALBOCICLIB	75 MG	New Entity
ANTINEOPLASTIC SYSTEMIC ENZYME INHIBITORS	IBRANCE	PALBOCICLIB	100 MG	New Entity
ANTINEOPLASTIC SYSTEMIC ENZYME INHIBITORS	IBRANCE	PALBOCICLIB	125 MG	New Entity
ANTIVIRALS, HIV-SPECIFIC, PROTEASE INHIBITORS	EVOTAZ	ATAZANAVIR SULFATE/COBICISTAT	300-150 MG	New Combination
ANTIVIRALS, HIV-SPEC, NON-PEPTIDIC PROTEASE INHIB	PREZCOBIX	DARUNAVIR/COBICISTAT	800-150 MG	New Combination

NEW INDICATIONS (EXISTING DRUGS)

DRUG	NEW INDICATION	DATE OF APPROVAL	LINKS
IMBRUVICA (IBRUTINIB)	WALDENSTRÖM'S MACROGLOBULINEMIA	JANUARY 29, 2015	Imbruvica® [package insert]. Pharmacyclics, Inc. January 2015.
VYVANSE (LISDEXAMFETAMINE DIMESYLATE)	MODERATE TO SEVERE BINGE EATING DISORDER	JANUARY 30, 2015	Vyvanse® [package insert]. Shire US Inc. January 2015.
LUCENTIS (RANIBIZUMAB)	DIABETIC RETINOPATHY IN PATIENTS WITH DIABETIC MACULAR EDEMA	FEBRUARY 6, 2015	Lucentis® [package insert]. Genentech, Inc. February 2015.
REVLIMID (LENALIDOMIDE)	MULTIPLE MYELOMA, IN COMBINATION WITH DEXAMETHASONE	FEBRUARY 17, 2015	Revlimid® [package insert]. Celgen Corporation. February 2015.

FDA NEWS/BULLETINS/ADVISORIES/SAFETY ALERTS

Virazole (Ribavirin Powder For Solution) by Valeant Pharmaceutical North America, LLC: Recall- Due to Microbial Contamination

[Posted 01/02/2015]

ISSUE: Valeant Pharmaceuticals North America LLC (VPNA) is issued a voluntarily recall of one lot of Virazole (ribavirin powder for solution), 100 mL, 6g Vial, 4-pack to the user level.

Inhalation of a non-sterile product with microbial contamination into the airways could increase the risk of respiratory infection. The risk is higher in patients who are immunocompromised (because of underlying disease), and are more susceptible.

BACKGROUND: Virazole is indicated for the treatment of hospitalized infants and young children with severe lower respiratory tract infections due to respiratory syncytial virus (RSV). Virazole is packaged in 100 mL, 6 g Vial, 4-pack NDC 00187-0007-14 which is to be reconstituted with 300 mL Sterile Water for Injection or Sterile Water for Inhalation (no preservatives added) and administered only by a small particle aerosol generator (SPAG-2). The affected Virazole lot is Lot No. 340353F with an expiration date of Oct-2018. Virazole was distributed in the U.S. and Australia.

RECOMMENDATION: VPNA is notifying its distributors and customers by mail and is arranging for return of all recalled product of this lot. This recall only affects this lot of Virazole; all other lots are not affected and are not involved in this recall.

Customers with questions regarding this recall can contact VPNA by phone at 800-321-4576 Monday - Friday, 8am - 5pm (Eastern) or by e-mail address at pharmcs@valeant.com. Consumers should contact their physician or healthcare provider for questions regarding this product.

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

Article link:

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm428700.htm>

Prescription and Over-the-Counter (OTC) Pain Medicines: Drug Safety Communication - FDA Review of Possible Risks of Pain Medicine Use During Pregnancy

[Posted 01/09/2015]

ISSUE: FDA is aware of and understands the concerns arising from recent reports questioning the safety of prescription and over-the-counter (OTC) pain medicines when used during pregnancy. As a result, FDA evaluated research studies published in the medical literature and determined they are too limited to make any recommendations based on these studies at this time. Because of this uncertainty, the use of pain medicines during pregnancy should be

carefully considered. FDA urges pregnant women to always discuss all medicines with their health care professionals before using them.

Severe and persistent pain that is not effectively treated during pregnancy can result in depression, anxiety, and high blood pressure in the mother. Medicines including nonsteroidal anti-inflammatory drugs (NSAIDs), opioids, and acetaminophen can help treat severe and persistent pain. However, it is important to carefully weigh the benefits and risks of using prescription and OTC pain medicines during pregnancy.

BACKGROUND: The published studies FDA reviewed reported on the potential risks associated with the following three types of pain medicines used during pregnancy. See the FDA Drug Safety Communication Data Summary section for more information about these studies.

RECOMMENDATION: Healthcare professionals should talk with each patient about the benefits and risks of analgesic use during pregnancy, which may differ among patients and by treatment indication. Continue to follow the existing recommendations in current drug labels regarding the use of analgesics during pregnancy.

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

Article link:

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm429604.htm>

Simulated IV Solutions from Wallcur: CDER Statement- FDA's Investigation into Patients being Injected [Posted 01/14/2015] [Posted 01/30/2015]

ISSUE: FDA and the Centers for Disease Control and Prevention (CDC) are continuing to investigate multiple instances of Wallcur's simulated intravenous (IV) saline products being administered to patients. These products are not sterile and should not be injected in humans or animals. So far, more than 40 patients have received infusions of the simulated saline products, and there have been many adverse events associated with these incidents including fever, chills, tremors and headache. Some patients were hospitalized, and there is one death associated with the use of these products; it is not known if this death is directly related to the use of the product.

BACKGROUND: Wallcur's simulated IV saline solution, Practi-0.9% sodium chloride solution, was shipped to medical clinics, surgical centers, and urgent care facilities in numerous states. While Sodium Chloride 0.9% Injection (IV normal saline) has been in tight supply, FDA has been working with manufacturers to increase supply. In addition, FDA is not objecting to the temporary distribution of additional IV normal saline from alternate sources Fresenius Kabi USA, Baxter Healthcare Corp., and B. Braun Medical Inc. Currently, there is supply available from several manufacturers as posted on FDA's website.

RECOMMENDATION: Healthcare Providers

Clinicians and office staff are encouraged to take steps to ensure IV solution simulation products are removed from office inventory to eliminate the possible injection of Wallcur simulated products into patients.

- Visually inspect all current IV saline solution bags. Ensure none of the bags are labeled “Wallcur,” “Practi-products,” “For clinical simulation,” or “Not for use in human or animal patients.”
- If you have products labeled with any of these words, or you suspect you may have received other products intended for training purposes, separate simulation products from existing inventory and contact your distributor for directions on how to return these products.
- If you have received Wallcur Practi-products by mistake, please contact the distributor, or Wallcur, LLC of San Diego for return instructions.
- Consider reviewing your office procedures and make sure there are procedures in place to visually inspect all future shipments of normal saline products to ensure they are for clinical use.

If you suspect that any Wallcur training IV products may have been administered to a patient, whether or not the incident has resulted in an adverse event:

- Evaluate all potentially exposed patients with new, or ongoing symptoms;
- Use appropriate treatment;
- Report suspected cases to the state health department; and
- Report any adverse events following use of these products to FDA’s MedWatch program online or at 1-800-332-1088.

Patients

- Patients who believe they received an injection of Wallcur simulated IV solution should contact their health care provider.
- Patients who received simulated IV saline almost immediately upon injection experienced fever, chills, muscle aches, headaches, and some required hospitalization. In most reported cases, these signs and symptoms were immediately recognized and patients received appropriate medical attention.
- You may also file a report of the incident through FDA’s MedWatch program, and assist the FDA with this ongoing investigation.
- If you know you will be receiving normal saline, ask your doctor or nurse to visually inspect the bag, and ensure they are using normal saline for human use. Ensure the bag is not labeled or printed with any of the following: “Wallcur,” “Practi-products,” “For clinical simulation” or “Not for use in human or animal patients.” If the saline bag contains any of these words, ask your health care provider NOT to administer the solution.

Wholesalers, Distributors, Suppliers

- Inspect your inventory and ensure you are not distributing simulated products as clinical use products.
- It is incumbent upon wholesalers, distributors, and suppliers to clearly and accurately label and distribute their products to prevent medical product mix-ups from occurring.
- If you suspect you may have distributed this product to clients by mistake, immediately attempt to recall the products and warn clients of the potential risks. You should also contact Wallcur, your distributor and file a report to FDA's MedWatch program.

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

Article link:

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm430360.htm>

0.9 Percent Sodium Chloride Injection, USP, 250 mL by Hospira: Recall - Particulate Matter [Posted 01/23/2015]

ISSUE: Hospira, Inc. announced a voluntary nationwide recall of one lot of 0.9% Sodium Chloride Injection, USP, 250 mL (NDC 0409-7983-02, Lot 44-002-JT, Expiry 1AUG2016) to the user level due to one confirmed customer report of particulate in a single unit. Hospira has identified the particulate as a human hair, sealed in the bag at the additive port area. To date, Hospira has not received reports of any adverse events associated with this issue for this lot.

Injected particulate material may result in local inflammation, phlebitis, and/or low-level allergic response. Capillaries which may be as small as the size of a red blood cell, approximately seven microns in diameter, may become occluded. Patients with preexisting condition of trauma or other medical condition that adversely affects the microvascular blood supply are at an increased risk.

BACKGROUND: The affected lot was distributed nationwide from September 2014 through November 2014. Hospira has initiated an investigation to determine the root cause and corrective and preventive actions.

RECOMMENDATION: Anyone with an existing inventory of the recalled lot should stop use and distribution and quarantine the product immediately. Customers should notify all users in their facility. Customers who have further distributed the recalled product should notify any accounts or additional locations which may have received the recalled product and instruct them if they have redistributed the product to notify their accounts, locations or facilities to the consumer level. Hospira has notified its direct customers via a recall letter and is arranging for impacted product to be returned to Stericycle in the United States. For additional assistance, call Stericycle at 1-877-877-0164 between the hours of 8 a.m. to 5 p.m. ET, Monday through

Friday. Hospira will provide allocation credits and make replacement product available for contracted customers.

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

Article link:

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm430941.htm>

Ketorolac Tromethamine Injection by Hospira: Recall - Particulate in Glass Vials

[Posted 02/11/2015]

ISSUE: Hospira announced a voluntary recall of ketorolac tromethamine injection, USP in the United States and Singapore due to potential particulate. The presence of particulate has been confirmed through a customer report of visible, floating particulate identified in glass flip-top vials. The particulate was identified as calcium-ketorolac crystals.

If particulates are not observed prior to administration, intramuscular (IM) or intravenous (IV) administration theoretically could result in localized inflammation, allergic reaction, granuloma formation or microembolic effects (IV only). Delay of therapy may occur due to particulates blocking the infusion of solution or due to observation of particulates at the point of care. Multiple lots are impacted by this recall. See the press release for affected lot numbers.

BACKGROUND: The lots were distributed from February 2013 to December 2014 in the United States and from January 2014 to July 2014 in Singapore. Hospira has not received reports of any adverse events associated with this issue for these lots to date. Hospira has initiated an investigation to determine the root cause and corrective and preventive actions.

RECOMMENDATION: Anyone with an existing inventory of the recalled lots should stop use and distribution, and quarantine the product immediately. This recall is being carried out to the medical facility/retail level. Customers who have further distributed the recalled product should notify any accounts or additional locations which may have received the recalled product and instruct them if they have redistributed the product to notify their accounts, locations or facilities to the medical facility/retail level. Hospira has notified its direct customers via a recall letter and is arranging for impacted product to be returned to Stericycle in the United States. For additional assistance, call Stericycle at 1-888-345-4680 between the hours of 8am to 5pm ET, Monday through Friday.

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

Article link:

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm433962.htm>

STUDIES and RECENT TOPICS

Abandonment rates indicate room in the anti-TNF market

January 15, 2015

A look at blockbuster anti-TNF drugs and the visibility of entrenched brands including AbbVie's Humira (adalimumab) and Johnson & Johnson's Remicade (infliximab), could make it seem like Biogen Idec's effort to break into the category will be daunting.

Article Link:

<http://www.mmm-online.com/abandonment-rates-indicate-room-in-the-anti-tnf-market/article/392791/>

Source: mmm-online.com

An inside look at the FDA's approach to speeding new drug approvals

January 15, 2015

The FDA enjoyed some industry kudos at the end of 2014 after handing out a record number of new drug approvals for the past decade. And now it's crunched the numbers for the year to underscore the kind of trends regulators see in the biopharma world.

Article Link:

<http://www.fiercebiotech.com/story/inside-look-fdas-approach-speeding-new-drug-approvals/2015-01-15>

Source: fiercebiotech.com

FDA concerned about drug-impaired drivers

January 15, 2015

Drugmakers are coming under scrutiny from federal regulators over the effects their medications may have on drivers while operating motor vehicles.

The Food and Drug Administration (FDA) announced Thursday it is looking to identify drugs that impair drivers' ability and increase their risk of being involved in a motor vehicle accident.

Article Link:

<http://thehill.com/regulation/229672-fda-concerned-about-drug-impaired-drivers>

Source: thehill.com

New FDA quality office to grade manufacturing operations

January 15, 2015

The FDA has shared details of plans for its Office of Pharmaceutical Quality (OPQ). Staffers plan to group drug production operations by category and release an average quality grade for each bucket, allowing manufacturers to see if they are outperforming their peers.

Article Link:

<http://www.fiercepharmamanufacturing.com/story/new-fda-quality-office-grade-manufacturing-operations/2015-01-15>

Source: fiercepharmamanufacturing.com

New Guidelines: Treat Obesity First

January 16, 2015

Will obesity drugs trim the need for diabetes, lipid, and hypertension drugs? Treat weight problems first then deal with comorbidities like dyslipidemia, hypertension, and impaired glucose tolerance, a new guideline urges.

Article Link:

<http://www.medpagetoday.com/Endocrinology/Obesity/49587>

Source: medpagetoday.com

Many Americans Taking Meds Not to Be Mixed With Alcohol

January 19, 2015

A substantial number of Americans who drink also take medications that should not be mixed with alcohol, new government research suggests. The findings were published online Jan. 16 in Alcoholism: Clinical & Experimental Research.

The findings were based on responses from 26,657 U.S. adults who took part in a government health survey. About three-quarters of men and two-thirds of women in the study were considered "current drinkers," because they'd had alcohol on at least one day in the past year

Article Link:

<http://www.physiciansbriefing.com/Article.asp?AID=695616>

Source: physiciansbriefing.com

The weights of passage

January 19, 2015

The Food and Drug Administration (FDA) recently approved the drug "liraglutide" (Saxenda) as a new mechanistic approach to the treatment of overweight and obesity. Like every drug on the brief list of FDA-approved weight loss medications it may be right for some people but not for others.

Article Link:

<http://thehill.com/blogs/congress-blog/healthcare/229808-the-weights-of-passage>

Source: thehill.com

Is High-Intensity Statin Therapy Underused?

January 19, 2015

The majority of patients do not fill high-intensity statin prescriptions following a hospitalization for a coronary heart disease event, according to a study published Jan. 19 in the Journal of the American College of Cardiology.

Article Link:

http://www.acc.org/latest-in-cardiology/articles/2015/01/16/14/30/is-high-intensity-statin-therapy-underused-acc-news-story?wt.mc_id=cvnewsdig

Source: acc.org

Genetic Changes to Ebola Virus Challenge Treatment Efforts

January 20, 2015

Genetic changes that have occurred in the Ebola virus over the last few decades could make it more difficult for scientists to find ways to treat the deadly pathogen, a new study says.

Many of the most promising experimental drugs being developed to fight Ebola bind to a target section of the virus's genetic sequence or a protein derived from that genetic sequence. If there are significant changes in Ebola's genetic sequence, these drugs may not work the researchers explained.

Article Link:

<http://consumer.healthday.com/infectious-disease-information-21/virus-health-news-697/genetic-changes-to-ebola-virus-challenge-treatment-efforts-695650.html>

Source: healthday.com

Teva Wins U.S. High Court Ruling to Delay Copaxone Rivals

January 20, 2015

Teva Pharmaceutical Industries Ltd. (TEVA) won a U.S. Supreme Court patent ruling that will help forestall generic competition to its top-selling Copaxone multiple-sclerosis drug.

Voting 7-2, the justices Tuesday in Washington gave a reprieve to a Teva patent that would protect Copaxone from rivals until September. The majority told a lower court to reconsider a ruling invalidating the patent.

Article Link:

<http://www.bloomberg.com/news/articles/2015-01-20/teva-wins-u-s-high-court-ruling-to-delay-copaxone-rivals-2->

Source: bloomberg.com

Study Rates Migraine Medications

January 20, 2015

The best medications to use if you suffer migraine headaches are listed in a new study.

Researchers reviewed recent scientific literature and concluded that a number of classes of drugs were effective for treating acute migraine.

These include triptans, dihydroergotamine (DHE) and many NSAIDs (nonsteroidal anti-inflammatory drugs that include aspirin, ibuprofen and naproxen). Also on the list: butorphanol nasal spray, and the combination medications sumatriptan/naproxen and acetaminophen/aspirin/caffeine.

Article Link:

<http://consumer.healthday.com/head-and-neck-information-17/headaches-health-news-345/new-guidelines-rate-migraine-medications-695553.html>

Source: healthday.com

Counterfeit Cialis found entering U.S. by mail: FDA

January 21, 2015

The U.S. Food and Drug Administration said counterfeit versions of the erectile dysfunction drug Cialis were found in the mail en route to a customer in the United States, and it is alerting consumers and doctors to be on the lookout for fakes. FDA laboratory analysis showed the counterfeit versions contain multiple active ingredients, which if used could result in adverse effects or harm, the agency said in a notice posted on its website on Wednesday.

Article Link:

<http://www.reuters.com/article/2015/01/21/us-cialis-fda-counterfeit-idUSKBN0KU2UM20150121>

Source: reuters.com

Merck Will No Longer Sell its Victrelis Hepatitis C Drug in the U.S.

January 21, 2015

Rival hepatitis C drugs from Merck and Vertex Pharmaceuticals made a big splash when they debuted in 2011, marking an advance in treatment of the liver disease and a lucrative new market segment. But now the Class of 2011 has almost sunk to the bottom, made obsolete by a newer wave of drugs, a sign of how rapidly the hepatitis C market is changing.

Article Link:

<http://blogs.wsj.com/pharmalot/2015/01/21/merck-will-no-longer-sell-its-victrelis-hepatitis-c-drug-in-the-u-s/>

Source: wsj.com

How to Build a Better Flu Vaccine than This Year's Fiasco

January 22, 2015

With this season's flu vaccine only protecting 1 in 4 people, scientists are working on new manufacturing techniques and virus-killing methods to update the creaky, 80-year-old process now used to inoculate the population.

Sometime this season, after many people got vaccinated, a strain of influenza that causes unusually serious illness evolved, letting the bug circumvent a protection that is still only about 60 percent effective in a good year. This year's vaccine is much worse, at just 23 percent, according to the U.S. Centers for Disease Control and Prevention.

Article Link:

<http://www.bloomberg.com/news/print/2015-01-22/how-to-build-a-better-flu-vaccine-than-this-year-s-fiasco.html>

Source: bloomberg.com

On painkillers and thinking about getting pregnant? Better talk to your doctor.

January 22, 2015

More than one-fourth of women who might become pregnant are getting prescriptions for opiod painkillers, such as Vicodin and Oxycontin, which can cause birth defects and other serious problems early in pregnancy, according to a report released Thursday by the Centers for Disease Control and Prevention.

Article Link:

<http://www.washingtonpost.com/news/to-your-health/wp/2015/01/22/many-women-who-might-become-pregnant-are-getting-prescription-painkillers-that-can-cause-birth-defects/>

Source: washingtonpost.com

FDA warns of Viagra in 'all natural' sexual health supplement: Tainted dietary Supplements

January 22, 2015

The Food and Drug Administration is warning consumers of generic Viagra in a sexual health supplement called Happy Passengers, sold online on various websites and in some retail stores.

The supplement, advertised on Amazon and other websites as "suitable for men of any age group" and acceptable for men with heart disease and high blood pressure, is one of many "natural" male enhancement products the FDA has found to contain sildenafil, the active ingredient in the FDA-approved prescription drug Viagra, which is used to treat erectile dysfunction (ED).

Article Link:

http://www.cleveland.com/healthfit/index.ssf/2015/01/fda_warns_of_viagra_in_all_nat.html

Source: Cleveland.com

Could Psychedelics Be An Effective Suicide Prevention Measure?

January 22, 2015

The new wave of research on the medical applications of psychedelic drugs has suggested that these substances may hold considerable promise as therapeutic interventions for a number of mental health conditions. And according to another new study, use of "classic" psychedelics -- psilocybin (magic mushrooms), LSD and mescaline -- may also be an effective suicide prevention measure.

Article Link:

http://www.huffingtonpost.com/2015/01/22/psychedelic-research_n_6515268.html

Source: huffingtonpost.com

FDA clears new medical app to track real-time glucose levels in diabetics

January 24, 2015

Doctors and other caregivers will soon be able to track the blood-sugar levels of diabetic patients by simply logging into a smartphone app, in the latest example of how mobile technologies are changing the health care landscape.

Article Link:

<http://www.washingtonpost.com/news/to-your-health/wp/2015/01/24/fda-clears-new-medical-app-to-track-real-time-glucose-levels-in-diabetics/>

Source: washingtonpost.com

Prices for Prescription Medicines Rose How Much Last Year?

January 26, 2015

The prices of prescription medicines is a front-and-center issue as the cost to treat everything from some of the rarest diseases to the most common afflictions is causing increasing concern among payers, physicians and consumers.

Article Link:

<http://blogs.wsj.com/pharmalot/2015/01/26/prices-for-prescription-medicines-rose-how-much-last-year/>

Source: wsj.com

Common medications linked to dementia, Alzheimer's disease, study finds

January 26, 2015

Prolonged use or higher doses of certain common drugs is linked to an increased risk of dementia, including Alzheimer's disease, a new study found.

The study, published Monday in *Jama Internal Medicine*, also unveiled evidence that the dementia risk persists even after the person stops taking the medication.

Article Link:

http://www.oregonlive.com/health/index.ssf/2015/01/common_medications_linked_to_d.htm

Source: oregonlive.com

More Pharma Execs Want FDA to Review Economic Value of Drugs: Survey.

January 27, 2015

As the pharmaceutical industry comes under increasing scrutiny over the prices of medicines, more drug makers are being asked to justify value. The controversy over the cost of new hepatitis C treatments is a shining example as pharmacy benefit managers lean on drug makers for bigger discounts.

Article Link:

<http://blogs.wsj.com/pharmalot/2015/01/27/more-pharma-execs-want-fda-to-review-economic-value-of-drugs-survey/>

Source: wsj.com

People Think Expensive Drugs Work Better, Study Shows

January 28, 2015

We've all heard of the placebo effect: just believing in the healing power of a pill is sometimes enough to make a person feel better, even when there's not medicine inside. Now, a new study shows that when people take a drug believing it's more expensive than it actually is, they tend to think the drug is working—even when it's just a placebo.

Article Link:

<http://time.com/3686707/placebo-effect-expensive-medications/#3686707/placebo-effect-expensive-medications/>

Source: time.com

The way we use antibiotics is broken. Blame nearly a century of drug marketing.

January 28, 2015

When our throats burn, we're conditioned to reach for antibiotics. When our noses run, we hound doctors for antibiotics. When we're too groggy to drive to the doctor, we search our medicine cabinets for leftover antibiotics. Four out of five Americans are prescribed the drugs every year, according to the Centers for Disease Control and Prevention. Up to half of the estimated 258 million prescriptions are unnecessary, the agency reports.

Article Link:

<http://www.washingtonpost.com/blogs/wonkblog/wp/2015/01/28/our-love-of-antibiotics-is-destroying-their-power-that-might-be-a-branding-problem/>

Source: washingtonpost.com

Drug Stimulates Brown Fat

January 28, 2015

A small study finds that an approved medication increases metabolic rate and the activity of thermogenic brown fat in men.

The stimulation of so-called brown fat—the energy-burning kind—is thought to be a potential therapeutic target for obesity. In a study published in *Cell Metabolism* this month (January 6), researchers gave volunteers an already-approved drug, which, as it turned out, appeared to stimulate metabolism and the activity of brown fat.

Article Link:

<http://www.the-scientist.com/?articles.view/articleNo/42008/title/Drug-Stimulates-Brown-Fat/>

Source: the-scientist.com

RECALLS*

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
	CLASS II				
Drugs	GINSENG KIANPI PIL, 60 capsules	All lots	Class II	Marketed Without An Approved NDA/ANDA: FDA analysis found this product to contain undeclared dexamethasone and cyproheptadine which are FDA approved drugs making this product an unapproved drug.	One and Zen
Drugs	Entertainer's Secret Throat Relief, 2.0 FL oz (59.2 mL), Honey Apple Flavor	Lot No. 141010, Best By Date: 10/2016; UPC Code: 728409847025	Class II	Microbial Contamination of Non Sterile Product; microbial assay reported unacceptable high plate counts and positive for E. Coli	Tropichem Research Labs, Inc.
Drugs	J-TAN D PD Drops (bromphenirame maleate 1 mg and pseudoephedrine hcl 7.5 mg/ teaspoon), 1 fl oz (30 mL) Bottle, Over the Counter.	Lot #: 7770, Expiry: 02/16	Class II	Labeling: Not Elsewhere Classified: Product is labeled "Dye Free" on front panel but contains Red Dye 40.	Jaymac Pharmaceuticals L.L.C.
Drugs	Gabapentin Capsules, USP 300 mg, 100-count bottles, Rx only	Lot #: GESB14011-A, Exp 12/15	Class II	Failed Tablet/Capsule Specifications: Complaints of empty capsules received.	Aurobindo Pharma USA Inc
Drugs	HydrALAZINE Hydrochloride Tablets, USP 25 mg, 100 count bottle Rx only	Lot 26708501, Exp. 01/17	Class II	Presence of Foreign Substance: Par Pharmaceutical, Inc. is recalling one lot of HydrALAZINE Hydrochloride tablets due to the presence of small aluminum particles.	Par Pharmaceutical Inc.
Drugs	Gabapentin Capsules,	Lot #s: a)	Class II	Failed Capsule/Tablet	Actavis

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
	USP, 400 mg, Rx Only, a) 100 capsules per bottle, NDC 14550-513-02, b) 500 Capsules per bottle, NDC 45963-557-50	G01889A2 Exp 06/2015, b) G01942A1 Exp 08/2015		Specifications: Actavis has received several complaints for clumping and breaking of capsules with some bottles showing popped out bottle bottom (round bottom) and creased labels from one distribution center.	Elizabeth LLC
Drugs	Gabapentin Capsules, USP, 300 mg, Rx Only, 100 capsules per bottle, 556-11	Lot #s: G01960A1, Exp 09/2015, G01967A1, Exp 10/2015	Class II	Failed Capsule/Tablet Specifications: Actavis has received several complaints for clumping and breaking of capsules with some bottles showing popped out bottle bottom (round bottom) and creased labels from one distribution center.	Actavis Elizabeth LLC
Drugs	Gabapentin Capsules, USP, 100 mg, Rx Only, a) 100 capsules per bottle, NDC 45963-555-11, b) 500 Capsules per bottle, NDC 45963-555-50	Lot #s: a) G01966A1, Exp 10/2015, b) G02004A1, Exp 03/2016	Class II	Failed Capsule/Tablet Specifications: Actavis has received several complaints for clumping and breaking of capsules with some bottles showing popped out bottle bottom (round bottom) and creased labels from one distribution center.	Actavis Elizabeth LLC
Drugs	Glutathione 200 mg/mL Injectable, packaged in a) 5 mL MDV (multiple dose vials), b) 30 mL MDV (multiple dose vials), and c) 100 mL MDV (multiple dose vials), Rx only	Lot #: 11142014@5, 10142014@17, 11032014@13, 08262014@6, 09162014@6, 06272014@12, 08052014@5, 07222014@18, 07222014@3,	Class II	Incorrect Product Formulation: An incorrect gas was used to remove the oxygen from the vial.	Right Value Drug Stores, Inc.

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
		06262014@11, 06182014@3			
Drugs	0.9% Sodium Chloride Injection, USP, 100mL, VisIV Container, Rx only	Lot #: 42-306-C6	Class II	Lack of Assurance of Sterility: The product has the potential for solution to leak at the administrative port.	Hospira Inc.
Drugs	Glycopyrrolate injection, 0.2 mg per mL (1 mg/5 mL), 5 mL Fill in 10 mL Syringe, Rx Only	Lot #: 20141218@41, Use by 3/18/2015; 20141226@24, Use by 3/26/2015	Class II	Labeling: Incorrect or missing Lot and/or Exp Date: Printing error caused an overlap in the "y" and "3" making the actual "Use By 3/2015" date appear to read "Use By8/2015".	SCA Pharmaceuticals
Drugs	CIPROFLOXACIN TABLETS, USP, 500 mg, 100 Tablets (10 tablets per blister card. 10 blister cards per carton),	Lot Number: 3034630; Expiration Date: 12/13; NDC: 51079-182-20	Class II	CGMP Deviations: Pharmaceuticals were produced and distributed with active ingredients not manufactured according to Good Manufacturing Practices	Mylan Institutional, Inc. (d.b.a. UDL Laboratories)
Drugs	LAMOTRIGINE TABLETS, 200 mg, 100 Tablets (10 tablets per blister card x 10 blister cards per carton), Rx only,	Lot Number: 3038124; Expiration Date: 1/14; NDC: 51079-866-20;	Class II	CGMP Deviations: Pharmaceuticals were produced and distributed with active ingredients not manufactured according to Good Manufacturing Practices	Mylan Institutional, Inc. (d.b.a. UDL Laboratories)
Drugs	Liposomal Amphotericin B 130 mg in dextrose bags	All products within expiry.	Class II	Lack of sterility assurance.	Walgreens Infusion Services
Drugs	Amikacin various strength in normal saline bags	All products within expiry.	Class II	Lack of sterility assurance.	Walgreens Infusion Services
Drugs	Aztreonam 1 gram in normal saline	All products within expiry.	Class II	Lack of sterility assurance.	Walgreens Infusion

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
					Services
Drugs	Cefepime various strengths in normal saline	All products within expiry.	Class II	Lack of sterility assurance.	Walgreens Infusion Services
Drugs	Cefoxitin various strength in normal saline bags	All products within expiry.	Class II	Lack of sterility assurance.	Walgreens Infusion Services
Drugs	Ceftazidime various strength in normal saline bags	All products within expiry.	Class II	Lack of sterility assurance.	Walgreens Infusion Services
Drugs	Imipenem/ cilastatin various strength in normal saline bags	All products within expiry.	Class II	Lack of sterility assurance.	Walgreens Infusion Services
Drugs	Ertapenem various strength in normal saline bags	All products within expiry.	Class II	Lack of sterility assurance.	Walgreens Infusion Services
Drugs	Piperacillin/ tazobactam various strength in normal saline bags	All products within expiry.	Class II	Lack of sterility assurance.	Walgreens Infusion Services
Drugs	Vancomycin various strengths in normal saline bags	All products within expiry.	Class II	Lack of sterility assurance.	Walgreens Infusion Services
Drugs	Cefuroxime various strengths in normal saline bags	All products within expiry.	Class II	Lack of sterility assurance.	Walgreens Infusion Services
Drugs	Meropenem various strengths in normal saline bags	All products within expiry.	Class II	Lack of sterility assurance.	Walgreens Infusion Services
Drugs	Nafcillin various strengths in sterile water for injection bags	All products within expiry.	Class II	Lack of sterility assurance.	Walgreens Infusion Services
Drugs	Cefazolin various strengths in normal saline bags	All products within expiry.	Class II	Lack of sterility assurance.	Walgreens Infusion Services
Drugs	Tobramycin various strengths in normal saline bags	All products within expiry.	Class II	Lack of sterility assurance.	Walgreens Infusion Services
Drugs	Gentamicin various strength in normal saline bags	All products within expiry.	Class II	Lack of sterility assurance.	Walgreens Infusion Services
Drugs	Daptomycin various strengths in normal saline bags	All products within expiry.	Class II	Lack of sterility assurance.	Walgreens Infusion Services
Drugs	Ceftriaxone various	All products	Class II	Lack of sterility	Walgreens

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
	strengths in normal saline	within expiry.		assurance.	Infusion Services
Drugs	Levofloxacin various strengths in normal saline	All products within expiry.	Class II	Lack of sterility assurance.	Walgreens Infusion Services
Drugs	Linezolid various strengths in dextrose	All products within expiry.	Class II	Lack of sterility assurance.	Walgreens Infusion Services
Drugs	Tigecycline various strengths in normal saline	All products within expiry.	Class II	Lack of sterility assurance.	Walgreens Infusion Services
Drugs	Acyclovir various strengths in normal saline	All products within expiry.	Class II	Lack of sterility assurance.	Walgreens Infusion Services
Drugs	Milrinone various strengths in dextrose	All products within expiry.	Class II	Lack of sterility assurance.	Walgreens Infusion Services
Drugs	Caspofungin various strengths in normal saline	All products within expiry.	Class II	Lack of sterility assurance.	Walgreens Infusion Services
Drugs	Dobutamine various strengths in dextrose	All products within expiry.	Class II	Lack of sterility assurance.	Walgreens Infusion Services
Drugs	Dopamine various strengths in dextrose	All products within expiry.	Class II	Lack of sterility assurance.	Walgreens Infusion Services
Drugs	Folic acid 1 mg/ 0.2 ml pre-drawn syringes	All products within expiry.	Class II	Lack of sterility assurance.	Walgreens Infusion Services
Drugs	Thiamine 100 mg/ ml vials	All products within expiry.	Class II	Lack of sterility assurance.	Walgreens Infusion Services
Drugs	Ranitidine various strengths in syringes	All products within expiry.	Class II	Lack of sterility assurance.	Walgreens Infusion Services
Drugs	Magnesium sulfate various strengths in sodium chloride	All products within expiry.	Class II	Lack of sterility assurance.	Walgreens Infusion Services
Drugs	Dehydrated alcohol vials	All products within expiry.	Class II	Lack of sterility assurance.	Walgreens Infusion Services
Drugs	Diphenhydramine 50 mg/ml vials	All products within expiry.	Class II	Lack of sterility assurance.	Walgreens Infusion Services

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
Drugs	Immune globulin g human various strengths	All products within expiry.	Class II	Lack of sterility assurance.	Walgreens Infusion Services
Drugs	L-cysteine various strengths	All products within expiry.	Class II	Lack of sterility assurance.	Walgreens Infusion Services
Drugs	Total parenteral nutrition various strengths	All products within expiry.	Class II	Lack of sterility assurance.	Walgreens Infusion Services
Drugs	Virazole (Ribavirin for Inhalation Solution, USP), Sterile Lyophilized For Administration by Aerosol Inhalation Only, Rx only, Contents: Four 6 g vials, 100 mL,	Lot #: 340353F, Exp 10/2018	Class II	Non-Sterility: Valeant's laboratory observed a positive microbial contamination of Virazole lot 340353F, during testing at the 12 month stability pull.	Valeant Pharmaceuticals North America LLC
	CLASS III				
Drugs	Deferoxamine various strengths in normal saline	All products within expiry.	Class III	Lack of sterility assurance.	Walgreens Infusion Services
Drugs	3M ESPE Clinpro 5000 (1.1% Sodium Fluoride), Anti-Cavity Toothpaste, 4 oz tube (NDC 48878-3130-04), Rx Only,	Product Code: 12115SM, Lot # 30131	Class III	Labeling: Incorrect or Missing Lot and/or Exp. Date - The subject lot is missing the lot number and expiration date stamp on the primary box..	3M Company/3m Espe Dental Products
Drugs	ACETAMINOPHEN and CODEINE PHOSPHATE ORAL SOLUTION USP, 120 mg/12 mg per 5 mL, packaged in a) 4 oz. (120 mL) bottles, NDC 0603-9013-54, UPC 3 0603-9013-54 8 and b) ONE PINT (473 mL) bottles, NDC 0603-9013-58, UPC 3 0603-9013-58 6, Rx only,	Lot #: a) L140H13B, Exp. 03/15; L001D14A. Exp. 08/15; b) L140H13A, Exp. 03/15; L205K13A, Exp. 05/15; L019L13A, L020L13A, Exp. 06/15; L001D14B,	Class III	Failed Impurities/Degradation Specifications: High out of specification results for the known impurity p-Aminophenol.	Qualitest Pharmaceuticals

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
		08/15; L091D14A, Exp. 10/15			
Drugs	Triamcinolone Acetonide Lotion USP, 0.025% is supplied in the following size: 60 mL (NDC 61748-219-60).	Lots 1413900, 1417200, 1417300, Exp. 02/15	Class III	Failed Impurities/Degradation Specifications: The known impurity went out of specification at 12 months stability point.	Akorn, Inc.

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

CURRENT DRUG SHORTAGES‡

Labetalol Injection

November 21, 2014

Reason for the Shortage

- Hospira had labetalol on shortage due to manufacturing delays and increased demand.
- Apotex discontinued their 4 mL vials (NDC 60505-0717-00) in February, 2010. The company could not provide a reason for the discontinuation.
- Sagent suspended production on labetalol 5 mg/mL 20 mL vials in July 2013.
- Sagent suspended production on labetalol 5 mg/mL 20 mL vials in July 2013 and 40 mL vials in February 2014.
- 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>

Trypan Blue 0.15% Ophthalmic Solution

November 21, 2014

Reason for the Shortage

- Dutch Ophthalmic has MembraneBlue on shortage due to difficulty in obtaining raw materials.
- There are no other manufacturers of trypan blue.
- Dutch Ophthalmic has VisionBlue 0.06% ophthalmic solution available (NDC 68803-0612-10). VisionBlue is used as an adjunct in cataract surgery.

Article link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1145>

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

Piperacillin Tazobactam Injection

January 26, 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.
- 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 2nd quarter 2015.
- 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>

Phenylephrine 2.5% and 10% Ophthalmic Solution

January 26, 2015

Reason for the Shortage

- Akorn stopped manufacturing phenylephrine ophthalmic solution in April 2014 and stopped distributing product on June 30, 2014.1
- Akorn is estimating launching new phenylephrine ophthalmic solution in early-March 2015.
- Alcon discontinued phenylephrine 2.5% ophthalmic solution with the Sandoz label in April 2014.
- Alcon discontinued Mydrin 2.5% ophthalmic solution in 2014.
- Hub discontinued phenylephrine 2.5% and 10% ophthalmic solution in 2013.
- Phenylephrine 2.5% and 10% from Paragon BioTeck is the only FDA-approved phenylephrine ophthalmic product. Paragon BioTeck supplies phenylephrine ophthalmic solution 2.5% and 10% and this is distributed by Bausch & Lomb (a division of Valeant).

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1105>

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

Hydromorphone Hydrochloride Injection

January 26, 2015

Reason for the Shortage

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

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=856>

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

Diltiazem Injection

January 26, 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>

Calcium Acetate Capsules

January 26, 2015

Reason for the Shortage

- Fresenius Medical cannot provide a reason for the shortage.
- Hawthorne states the reason for the shortage was manufacturing delay.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1002>

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

Amikacin Injection

January 26, 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.
- Hospira discontinued amikacin in May, 2010 due to a raw material shortage.
- Teva's product was unavailable due to manufacturing delays.
- Sandoz discontinued Amikin injection in 2006.
- Heritage launched amikacin injection in March 2014.

Article Link:

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

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

Acyclovir Injection

January 26, 2015

Reason for the Shortage

- Fresenius Kabi (formerly APP) is not manufacturing acyclovir lyophilized powder to concentrate on supplying the solution for injection.¹
- Ben Venue stopped production in its plant in Bedford, Ohio and closed in July 2014.²
- AuroMedics introduced acyclovir injection in February 2014.³

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=467>

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

Memantine Hydrochloride

January 27, 2015

Reason for the Shortage

- Forest states the reason for the shortage of Namenda XR capsules is manufacturing delay.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1082>

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

Testosterone Cypionate Intramuscular Injection

January 28, 2015

Reason for the Shortage

- 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.

Article Link:

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

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

Sterile Water Irrigation

January 28, 2015

Reason for the Shortage

- Baxter has sterile water for irrigation on shortage due manufacturing delays.
- BBraun only has product available for existing customers.
- Hospira only has product available for existing customers.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1120>

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

Sodium Chloride 0.9% Irrigation

January 28, 2015

Reason for the Shortage

- Baxter has 0.9% sodium chloride irrigation on shortage due manufacturing delays.
- BBraun has 0.9% sodium chloride irrigation on shortage due to increased demand and only has product available for existing customers.
- Hospira has 0.9% sodium chloride irrigation on shortage due manufacturing delays and only has product available for existing customers.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1118>

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

Posaconazole Oral Suspension

January 28, 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>

Moxifloxacin Injection

January 28, 2015

Reason for the Shortage

- Merck cannot provide a reason for the shortage.
- Merck is the sole supplier of moxifloxacin intravenous presentations. Moxifloxacin tablets are not affected by this shortage.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1151>

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

Iron Dextran Injection

January 28, 2015

Reason for the Shortage

American Regent cannot provide a reason for the shortage.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1069>

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

Dexmethylphenidate Hydrochloride

January 28, 2015

Reason for the Shortage

- Teva had product on allocation and shortage due to DEA quotas that are projected annually.
- Mylan could not provide a reason for the shortage.
- Novartis stated the reason for the shortage was increased demand.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1079>

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

Cefpodoxime

January 28, 2015

Reason for the Shortage

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

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=793>

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

Tolterodine Tartrate Extended Release Capsules

January 29, 2015

Reason for the Shortage

- Mylan discontinued tolterodine extended release 2 mg and 4 mg capsules in 90 count bottles in April 2014.
- Teva could not provide a reason for the shortage.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1114>

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

Sincalide Injection

January 29, 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>

Oxycodone/Acetaminophen Oral Solution

January 29, 2015

Reason for the Shortage

- Roxane states that the reason for the shortage is that they are validating a new source for raw materials.
- Roxane discontinued oxycodone/acetaminophen 5 mL unit-dose cups in July 2014.
- Oxycodone/acetaminophen oral solution is not available from other manufacturers or in other concentrations.
- This shortage does not affect single-ingredient oxycodone solutions or oxycodone/acetaminophen solid oral dosage forms.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1117>

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

Metronidazole Injection

January 29, 2015

Reason for the Shortage

- Hospira has metronidazole injection on back order due to manufacturing delays.
- BBraun is allocating metronidazole injection due to increased demand for the product.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=643>

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

Famotidine Injection

January 29, 2015

Reason for the Shortage

- Ben Venue stopped production in its plant in Bedford, Ohio and closed in July 2014.¹
- West-Ward states the shortage was due to manufacturing delays.²
- Oral famotidine products are not affected by this shortage.
- Pfizer launched famotidine injections in March, 2012.³
- Mylan Institutional acquired famotidine injections from Pfizer on December 6, 2013.⁴

Article Link:

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

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

Prednisone Tablets

January 30, 2015

Reason for the Shortage

- Cadista states the shortage was due to a raw materials shortage.
- Perrigo discontinued prednisone tablets in 2013.
- Qualitest discontinued prednisone 20 mg tablets in August 2013.
- West-Ward states the reason for the shortage is manufacturing delays.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=930>

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

Midazolam Injections

January 30, 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.
- Hospira discontinued midazolam 5 mg/mL 1 mL iSecure syringes in July 2011.
- Fresenius Kabi (formerly APP) 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 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>

Mannitol Injection

January 30, 2015

Reason for the Shortage

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

Article Link:

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

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

Acamprosate Calcium Tablets

January 30, 2015

Reason for the Shortage

- Glenmark Pharmaceuticals 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>

Zinc Injection

February 2, 2015

Reason for the Shortage

- Hospira states the shortage of zinc chloride injection is due to manufacturing delays.
- Hospira is the only manufacturer of zinc chloride injection.
- American Regent states the shortage of zinc sulfate injection is due to manufacturing delays.
- FDA was allowing temporary importation of zinc gluconate trihydrate 1 mg/mL 10 mL vials from Aguetant Laboratories in France. This product was being distributed through Baxter Healthcare but the imported lots have expired and Baxter is not importing more product.

Article Link:

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

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

Promethazine Injection

February 2, 2015

Reason for the Shortage

- Teva states the shortage is due to manufacturing delays.
- West-Ward states the shortage was due to manufacturing delays. The company has also changed the NDC numbers for products that were formerly Baxter products.

- 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>

Paclitaxel Injection

February 2, 2015

Reason for the Shortage

- Fresenius Kabi (formerly APP) had paclitaxel on shortage due to increase demand for the product.¹
- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired paclitaxel injection from Bedford in July 2014. West-Ward is not actively marketing paclitaxel.^{2,3}
- Teva has paclitaxel on shortage due to manufacturing delays.⁴
- Sandoz has paclitaxel on back order due to a raw material shortage.⁵
- Hospira had paclitaxel on shortage due to increased demand.^{6,7}
- Sagent has paclitaxel on shortage due to increased demand.⁸
- Sagent discontinued paclitaxel 30 mg/5 mL and 100 mg/16.7 mL presentations in October 2014.⁸
- Pfizer launched paclitaxel 100 mg and 300 mg vials in March, 2012 and launched the 30 mg vials in April, 2012.⁹
- Mylan Institutional acquired paclitaxel injection from Pfizer on December 7, 2013.^{9,10}
- WG Critical Care launched paclitaxel injection in September 2014.¹¹

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=790>

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

Methylprednisolone Acetate Injection

February 2, 2015

Reason for the Shortage

- Sandoz and Teva could not provide a reason for the shortage.
- Pfizer had Depo-Medrol injection on shortage due to manufacturing delay.

Article Link:

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

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

Echothiophate Powder for Ophthalmic Solution

February 2, 2015

Reason for the Shortage

Pfizer is the only manufacturer of echothiophate powder for ophthalmic solution (Phospholine Iodide).

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=85>

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

Divalproex Sodium Delayed Release Tablets

February 2, 2015

Reason for the Shortage

- Caraco, Teva and Unichem Laboratories cannot provide a 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>

Desmopressin Injection

February 2, 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>

Cefotetan Disodium Injection

February 2, 2015

Reason for the Shortage

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

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1097>

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

Carboplatin Solution for Injection

February 2, 2015

Reason for the Shortage

- Bedford discontinued carboplatin in May, 2011 to concentrate on the manufacturing of other products.¹
- Teva has carboplatin injection on allocation due to increased demand.⁴
- Fresenius Kabi has carboplatin on shortage due to increased demand for the product.⁵
- Sandoz has carboplatin on shortage due to manufacturing delays.⁶

- Sagent launched carboplatin in November 2013.⁷

Article Link:

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

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

Acyclovir Suspension

February 2, 2015

Reason for the Shortage

- Akorn could not provide a reason for the shortage.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1018>

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

Heparin Premixed Bags

February 3, 2015

Reason for the Shortage

- Baxter and BBraun have 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>

Digoxin Injection

February 3, 2015

Reason for the Shortage

- West-Ward states the shortage is due to manufacturing delays

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=748>

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

Dextran Low Molecular Weight (Dextran 40), 10% Injection

February 3, 2015

Reason for the Shortage

- Hospira states the reason for the shortage is manufacturing delay.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1108>

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

Calcium Gluconate Injection

February 3, 2015

Reason for the Shortage

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

- Fresenius Kabi had calcium gluconate on shortage due to increase demand for the product.
- 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>

Bupivacaine with epinephrine Injection

February 3, 2015

Reason for the Shortage

- Fresenius Kabi (formerly APP) had Sensorcaine with epinephrine on shortage due to increased demand for the product.
- Hospira has bupivacaine with epinephrine on shortage due to manufacturing delays.

Article Link:

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

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

Bupivacaine with epinephrine Injection

February 3, 2015

Reason for the Shortage

- Fresenius Kabi (formerly APP) had Sensorcaine with epinephrine on shortage due to increased demand for the product.
- Hospira has bupivacaine with epinephrine on shortage due to manufacturing delays

Article Link:

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

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

Trace Elements Injection

February 4, 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>

Phytonadione (Vitamin K) Injection

February 4, 2015]

Reason for the Shortage

- Amphastar has vitamin K injection on shortage due to increased demand for the product.
- Hospira had vitamin K injection on shortage

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=852>

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

Oxacillin Sodium Injection

February 4, 2015

Reason for the Shortage

- Auromedics states the reason for the shortage is increased demand.
- Sagent states the reason for the shortage is manufacturing delay.
- Sandoz states the reason for the shortage is difficulty obtaining the active pharmaceutical ingredient.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1121>

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

Methylene Blue Injection

February 4, 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>

Lorazepam injectable presentations

February 4, 2015

Reason for the Shortage

- Bedford discontinued lorazepam in May, 2011 to concentrate on the manufacturing of other products.
- West-Ward acquired Baxter's lorazepam injection products in May, 2011. NDC numbers for the lorazepam and Ativan products were changed in April, 2012.
- West-Ward had Ativan on back order due to increase surplus of the lorazepam presentations.
- Hospira states lorazepam vials are on shortage due to increased demand and manufacturing delays. The 1 mL iSecure syringes were discontinued in September 2011.
- Akorn increased production to help meet demand.
- Amphastar had lorazepam 2 mg/mL vials on shortage due to increased demand.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=747>

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

Vecuronium Bromide Injection

February 5, 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.
- 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>

Thiotepa for Injection

February 6, 2015

Reason for the Shortage

- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired several products from Bedford Laboratories in July 2014 including thiotepa injection. West-Ward is not actively marketing thiotepa injection at this time.
- FDA is allowing temporary importation of Tepadina (thiotepa), from Adienne Srl in Italy. Product may be ordered directly through Adienne Srl. The solution is similar in formulation to US thiotepa. The main differences between the two products are listed below:
 - Tepadina comes in 15 mg and 100 mg vials while the US thiotepa from Bedford only comes in a 15 mg vial. Reconstitution of the products should still yield a final concentration of 10 mg/mL and therefore use caution in choosing vial size and volume of diluent.
 - Tepadina is indicated for different uses and therefore different dosing regimens are on the Europe labeling compared to US labeling, but it is the same product as in the US.
 - The bar coding for the Italian product will not provide correct information to bar code readers since the manufacturing code is not an NDC number. More information on the product packaging and ordering procedures can be found online.
- Adienne Srl is supplying Tepadina directly to hospitals and not through wholesalers. Orders can be placed directly with Adienne. Orders are shipped Monday through Wednesday to ensure product can arrive prior to the weekend to prevent temperature deviations.
- There are no other manufacturers of thiotepa for injection.

Article Link:

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

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

Tamsulosin Hydrochloride Capsules

February 6, 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>

Sodium Phosphate Injection

February 6, 2015

Reason for the Shortage

- American Regent has sodium phosphate injection on back order due to manufacturing delays.
- American Regent has issued a statement that all lots of sodium phosphate have potential for crystallization. Do not use if any particles are present.
- Hospira had sodium phosphate injection on shortage due to manufacturing delays.
- In cooperation with FDA, Fresenius Kabi USA is providing Glycophos (sodium glycerophosphate) injection to the US market to help alleviate the shortage. Glycophos is manufactured in an FDA-approved facility in Norway by Fresenius Kabi AG.
- Fresenius Kabi launched sodium phosphate injection in mid-January 2014.

Article Link:

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

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

Ammonium Chloride Injection

February 6, 2015

Reason for the Shortage

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

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=933>

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

Secretin Injection

February 9, 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>

Proparacaine Hydrochloride Ophthalmic Solution

February 9, 2015

Reason for the Shortage

- Sandoz cannot provide a reason for the shortage.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1147>

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

Physostigmine Salicylate Injection

February 9, 2015

Reason for the Shortage

- Akorn states the shortage is due to increased demand.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1143>

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

Nitroglycerin Injection

February 9, 2015

Reason for the Shortage

- American Regent has recently upgraded their manufacturing plant. Product will become available in stages as production resumes.¹
- Hospira discontinued nitroglycerin injection.²
- Baxter had nitroglycerin premixes on shortage due to a raw material supply issue.³
- In cooperation with FDA, Arbor Pharmaceuticals was importing glyceryl trinitrate (Nitronal) injection to the US market to help alleviate the national shortage. This glyceryl trinitrate is manufactured in an FDA-approved facility in Germany by Pohl Boskamp. Glyceryl trinitrate is another name for nitroglycerin.⁴

Article Link:

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

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

Nafcillin Sodium

February 9, 2015

Reason for the Shortage

- AuroMedicss and Fresenius Kabi state the reason for the shortage is increased demand.
- Sagent stated the reason for the shortage was a manufacturing delay.
- 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>

Liotrix Tablets

February 9, 2015

Reason for the Shortage

- Thyrolar tablets from Forest Laboratories are on back order due to manufacturing changes.

Article Link:

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

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

Lidocaine Hydrochloride Oral Topical Solution (Viscous) 2%

February 9, 2015

Reason for the Shortage

- Akorn could not provide a reason for the shortage.
- Roxane states the shortage is 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>

Calcium Chloride Injection

February 9, 2015

Reason for the Shortage

- American Regent has calcium chloride on shortage due to manufacturing delays.
- Amphastar has calcium chloride on shortage due to increased demand.
- Hospira has calcium chloride on shortage due to manufacturing delays.
- Mylan Institutional acquired calcium chloride injection from Amneal in March 2014. FDA had previously given Amneal permission for temporary importation of calcium chloride 100 mg/mL 10 mL syringes from the United Kingdom. Mylan Institutional has FDA permission to sell the remaining imported calcium chloride product.

Article Link:

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

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

Vasopressin Injection

February 11, 2015

Reason for the Shortage

- American Regent has vasopressin injection on shortage due to manufacturing delays.
- Par Sterile Products (formerly JHP) discontinued Pitressin injection in November 2014.
- Par Sterile Products introduced Vasostriect injection in November 2014. This is the only FDA-approved vasopressin injection.
- Fresenius Kabi has vasopressin on shortage due to increased demand for the product.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=795>

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

Tobramycin Injection

February 11, 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.
- Pfizer acquired tobramycin injection from Akorn in early-May, 2011.
- Pfizer divested tobramycin injection to Mylan Institutional on December 6, 2013.
- Mylan Institutional could not provide a reason for the shortage.
- Mylan Institutional has changed the NDC numbers of their tobramycin presentations.

Article Link:

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

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

Phenazopyridine Hydrochloride

February 11, 2015

Reason for the Shortage

- Amneal Pharmaceuticals and SDA Laboratories discontinued phenazopyridine tablets.
- Avkare and Marlex could not provide a reason for the shortage.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1144>

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

Oxytocin Injection

February 11, 2015

Reason for the Shortage

- Fresenius Kabi, USA (formerly APP) states the shortage is due to increased demand.
- Par Sterile Products (formerly JHP) discontinued generic oxytocin injection in July 2014.
- West-Ward states the shortage is due to stock becoming short-dated.

Article Link:

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

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

Metoprolol Injection

February 11, 2015

Reason for the Shortage

- American Regent has metoprolol injection on shortage due to manufacturing delays.
- Fresenius Kabi, Hospira and Sagent state the shortage was due to increased demand for the product.
- Ben Venue stopped production in its plant in Bedford, Ohio and closed in July 2014.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=813>

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

Labetalol Injection

February 11, 2015

Reason for the Shortage

- Hospira has labetalol on shortage due to manufacturing delays and increased demand.
- Apotex discontinued their 4 mL vials (NDC 60505-0717-00) in February, 2010. The company could not provide a reason for the discontinuation.
- Sagent suspended production on labetalol 5 mg/mL 20 mL vials in July 2013.
- Sagent suspended production on labetalol 5 mg/mL 20 mL vials in July 2013 and 40 mL vials in February 2014.
- 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>

Ketorolac Tromethamine Injection

February 11, 2015

Reason for the Shortage

- Fresenius Kabi states the shortage was due to manufacturing delays.¹
- Hospira has ketorolac on shortage due to manufacturing delays for quality improvement activities and increased demand for the product.²
- 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.³
- West-Ward has ketorolac injection on shortage due to manufacturing delays.⁴
- Ben Venue closed its plant in Bedford, Ohio in July 2014.⁵
- FDA imposed an import ban in mid-2013 on several Wockhardt products including ketorolac.⁶

Article Link:

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

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

Citric acid and Potassium Citrate Oral**February 11, 2015**Reason for the Shortage

Cypress Pharmaceuticals had Cytra-K crystals on back order due to a raw material supply issue.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1080>

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

Benztropine Injection**February 11, 2015**Reason for the Shortage

- American Regent has benztropine injection on back order due to manufacturing delays.
- Fresenius Kabi USA recalled benztropine injection due to potential for glass particles in the vials. Product may have been under APP or Nexus labels. Detailed information on the recall can be found online.

Article Link:

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

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

Azathioprine Tablets**February 11, 2015**Reason for the Shortage

- Roxane, Salix, and Zydus cannot 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>

L-Cysteine Hydrochloride Injection**February 12, 2015**Reason for the Shortage

- American Regent has L-cysteine hydrochloride injection on back order due to manufacturing delays.
- Sandoz cannot provide a reason for the shortage.

Article Link:

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

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

Etomidate Injection

February 12, 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 manufacturing delays.
- Mylan Institutional acquired etomidate injection from Pfizer on December 6, 2013. Mylan Institutional divested some presentations of etomidate injection to JHP Pharmaceuticals in April 2014.
- [Mylan recalled](#) 10 lots of etomidate injection with the Pfizer label in February 2014. The recall was due to the presence of particulate matter and missing lot numbers and expiration dates on the vials.
- Par Pharmaceuticals acquired JHP Pharmaceuticals in early 2014. 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>

Esmolol Injection

February 12, 2015

Reason for the Shortage

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

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=833>

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

Clindamycin Injection

February 12, 2015

Reason for the Shortage

- Pfizer states the Cleocin Add-Vantage vials are on shortage due to manufacturing delays.
- Hospira has clindamycin injection on shortage due to manufacturing delays.
- Akorn launched clindamycin injection in June 2013.
- Sandoz had clindamycin injection on shortage due to increased demand.
- Sagent has clindamycin injection on shortage due to manufacturing delays.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1029>

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

Haloperidol Lactate Injection

February 13, 2015

Reason for the Shortage

- 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.
- Mylan Institutional could not provide a reason for the shortage.
- Sagent had haloperidol lactate on shortage due to manufacturing delays.
- Teva has haloperidol lactate on shortage due to manufacturing delays.
- Mylan Institutional acquired haloperidol lactate injection from Pfizer on December 6, 2013.
- Patriot Pharmaceuticals states the reason for the shortage was increased demand.

Article Link:

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

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

Ephedrine Injection

February 13, 2015

Reason for the Shortage

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

Article Link:

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

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

Dexamethasone Sodium Phosphate

February 13, 2015

Reason for the Shortage

- American Regent has dexamethasone sodium phosphate on shortage due to manufacturing delays.¹
- Fresenius Kabi states the dexamethasone sodium phosphate shortage is due to supply and demand issues.²
- Baxter could not provide a reason for the shortage. Baxter sold several products to West-Ward in mid-2011.³
- West-Ward had dexamethasone sodium phosphate injection on shortage due to increased demand.⁴
- Pfizer divested all dexamethasone presentation to Mylan Institutional on December 6, 2013.^{4,5}
- Mylan Institutional states the shortage is due to increased demand.⁵

Article Link:

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

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

Dacarbazine Injection

February 13, 2015

Reason for the Shortage

- Fresenius states the reason for the shortage is increased demand.⁴
- Teva and Hospira had dacarbazine on back order due to manufacturing delays.^{1,3}
- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired dacarbazine injection from Bedford in July 2014. West-Ward is not actively marketing dacarbazine injection at this time.^{2,5}

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=949>

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

Ciprofloxacin Injection

February 13, 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>

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

Chorionic Gonadotropin (Human) Injection

February 13, 2015

Reason for the Shortage

- Merck (formerly Schering-Plough) states their product is on allocation to prevent use in the gray market.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=382>

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

AlprostadiL Products

February 13, 2015

Reason for the Shortage

- Bedford discontinued alprostadiL in May, 2011 to concentrate on the manufacturing of other products.
- Teva's product is on long-term back order due to manufacturing difficulties.²
- Pfizer's Caverject Impulse was on backorder while the product was reformulated. The company has discontinued Caverject injection 10 mcg lyophilized powder and 20 mcg/mL solution for injection.³
- Actient has acquired several products from Schwarz (UCB) including Edex cartridges in 2010.^{4,5}
- Auxilium acquired Actient's urology products including Edex cartridges in April 2013.⁶
- Meda Pharmaceuticals has acquired Muse from Vivus.^{7,8}

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=474>

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

Acetaminophen and Codeine Phosphate 300 mg/30 mg Tablets

February 13, 2015

Reason for the Shortage

- Mallinckrodt states the shortage is due to production delays and increased demand.
- Aurobindo 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>

Lactated Ringer's Injection Bags

February 16, 2015

Reason for the Shortage

- Baxter has lactated ringer's on shortage due to increased demand.¹
- BBraun has lactated ringer's on allocation due to increased demand.²
- Hospira cites increased demand as the reason for the shortage.³

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1078>

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

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

February 16, 2015

Reason for the Shortage

- Sanofi Pasteur states the reason for the Daptacel shortage is manufacturing delay.^{1,2,3}
- Sanofi Pasteur discontinued Tripedia in 2011.

Article Link:

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

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

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

February 16, 2015

Reason for the Shortage

Sanofi Pasteur states the reason for the shortage is manufacturing delay, which will reduce supplies below current demand.

Article Link:

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

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

Ciprofloxacin Immediate-Release Tablets

February 16, 2015

Reason for the Shortage

- Ranbaxy has an FDA import ban on several of their products manufactured in India.
- Carlsbad Technology discontinued ciprofloxacin tablets in 2014.
- Marlex is unable to provide a reason for their shortage.
- Major discontinued their ciprofloxacin immediate-release tablets in February, 2010.
- Teva discontinued their ciprofloxacin immediate-release tablet, unit dose presentations in June, 2010.
- Schering has discontinued all Cipro immediate-release tablet presentations.
- UDL has discontinued all ciprofloxacin immediate-release 250 mg unit-dose tablets.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=572>

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

Black Widow Antivenin (Latrodectus Mactans)

February 16, 2015

Reason for the Shortage

- Merck has low inventory of Antivenin Latrodectus Mactans.

Emergency supplies are available for patients with symptoms due to a bite by the black widow spider within 24 hours of contacting Merck. The company cannot estimate when regular distribution will resume.

Article Link:

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

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

Atropine Sulfate Injection

February 16, 2015

Reason for the Shortage

- American Regent states the shortage was due to manufacturing delays.
- Hospira states the shortage is due to manufacturing delays.
- Amphastar has atropine on shortage due to increased demand.

Article Link:

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

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

Ranitidine Injection

February 17, 2015

Reason for the Shortage

- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired ranitidine injection from Bedford in July 2014. West-Ward is not actively marketing ranitidine injection.¹
- Covis has Zantac on shortage due to capacity issues at the manufacturer.²

- Oral ranitidine products are not affected by this shortage.

Article Link:

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

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

Pantoprazole Injection

February 17, 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>

Lidocaine Injection

February 17, 2015

Reason for the Shortage

- Hospira has lidocaine presentations on shortage due to manufacturing delays and increased demand.
- Fresenius Kabi, USA (formerly APP) has Xylocaine and lidocaine presentations on shortage due to increased demand for the product.
- Amphastar had lidocaine 2% emergency syringes on shortage due to increased demand for the product.
- BBraun has lidocaine and dextrose premixed bags on shortage due to increased demand for the product.
- Baxter discontinued two lidocaine and dextrose premixed bag presentations in March, 2012.
- AuroMedics introduced lidocaine injection in February 2014.

Article Link:

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

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

Hydralazine Injection

February 17, 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 increased demand.

Article Link:

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

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

Vancomycin Hydrochloride Injection

February 18, 2015

Reason for the Shortage

- Hospira has vancomycin on shortage due to increased demand.
- Fresenius Kabi (formerly APP) has vancomycin injection on shortage due to increased demand.
- Sagent has vancomycin on shortage due to increased demand.
- Akorn has sold their vancomycin products to Pfizer and stopped distributing on April 29, 2011.
- Mylan Institutional acquired vancomycin injection from Pfizer on December 6, 2013.
- Mylan Institutional (formerly Bioniche) has acquired multiple products from Generamedix, including vancomycin hydrochloride.
- Mylan Institutional discontinued two vancomycin presentations in September 2013.
- Pfizer acquired multiple products from Akorn, including vancomycin hydrochloride in early-May, 2011.

Article Link:

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

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

Sodium Chloride 0.45% Injection Bags

February 18, 2015

Reason for the Shortage

- Baxter has 0.45% sodium chloride on shortage due to increased demand.
- BBraun had 0.45% sodium chloride on allocation due to increased demand.
- Hospira cited increased demand as the reason for the shortage.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1083>

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

Rocuronium Injection

February 18, 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 was 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.
- The Medicines Company launched rocuronium in early 2014.

Article Link:

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

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

Octreotide Injection

February 18, 2015

Reason for the Shortage

- Caraco cannot provide a reason for the shortage.
- Fresenius Kabi (formerly APP) reports that the shortage was due to increased demand for the product.
- Sandoz discontinued octreotide injection in 2nd quarter 2013.
- Sagent has octreotide on shortage due to increased demand for the product.
- Teva has octreotide on shortage due to manufacturing delays.
- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired octreotide injection from Bedford in July 2014. West-Ward is not actively marketing octreotide injection except available 1000 mcg/mL, 5 mL vial.
- Wockhardt has octreotide on back order due to an import ban.
- Sandostatin LAR presentations from Novartis are not affected by this shortage

Article Link:

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

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

Methyldopate Injection

February 18, 2015

Reason for the Shortage

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

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=844>

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

Methotrexate Injection

February 18, 2015

Reason for the Shortage

- Hospira states the reason for the shortage was a manufacturing delay.
- Sandoz recalled two lots of methotrexate 40 mL preservative-free vials in May 2013 due to discover of particulate matter during routine quality control inspection.
- Mylan Institutional acquired methotrexate injection from Pfizer on December 6, 2013.
- Mylan Institutional divested three presentations of methotrexate injection to Intas (Accord Healthcare) in April 2014.
- Bioniche was acquired by Mylan Institutional in September, 2011.
- Teva discontinued methotrexate 4 mL vials in October 2013 due to business reasons.
- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired several products from Bedford Laboratories in July 2014 including methotrexate injection. West-Ward is not actively marketing methotrexate injection.

Article Link:

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

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

Doxorubicin Injection**February 18, 2015**Reason for the Shortage

- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired Adriamycin injection from Bedford in July 2014. West-Ward is not actively marketing Adriamycin injection at this time.¹
- Pfizer had doxorubicin solution for injection on shortage due to shipping delays.⁵
- Sagent introduced doxorubicin injection in November 2013.⁶
- Mylan Institutional acquired doxorubicin lyophilized powder from Pfizer on December 6, 2013.⁷
- Teva could not provide a reason for the shortage.²

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=464>

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

Disopyramide Phosphate Controlled-release Capsules**February 18, 2015**Reason for the Shortage

- Pfizer had their 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>

Dextrose 5% Injection Large Volume Bags**February 18, 2015**Reason for the Shortage

- Baxter states the shortage is due to increased demand.¹
- BBraun had 5% dextrose on allocation due to increased demand.²
- Hospira states the shortage is due to increased demand and manufacturing delays.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1081>

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

Daunorubicin Hydrochloride Injection**February 18, 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.¹

- Teva's daunorubicin injection has a 12 month shelf-life after manufacturing.²
- Teva states daunorubicin was on back order due to manufacturing delays.²

Article Link:

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

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

Cidofovir Injection

February 18, 2015

Reason for the Shortage

- [Gilead](#) recalled one lot of Vistide on February 4, 2013, due to particulate matter in some vials.
- Gilead discontinued [Vistide injection](#) in July 2014.
- Mylan Institutional launched cidofovir injection in mid-March 2013.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=994>

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

Choline Magnesium Trisalicylate

February 18, 2015

Reason for the Shortage

Marlex could not provide a reason for their shortage.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=556>

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

Chloramphenicol Sodium Succinate Injection

February 18, 2015

Reason for the Shortage

- [Fresenius Kabi](#) has chloramphenicol injection on back order due to a raw material shortage.
- Fresenius Kabi is the sole supplier of chloramphenicol injection.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1068>

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

Bupropion Hydrochloride 24 hour ER Tablets

February 18, 2015

Reason for the Shortage

- Actavis began transitioning to new NDC numbers in February 2015.
- Par states the reason for the shortage is increased demand of product.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1106>

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

Ampicillin Sulbactam

February 18, 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>

Tacrolimus Capsules

February 19, 2015

Reason for the Shortage

- Novartis discontinued all Hecoria presentations in February 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>

Synthetic Conjugated Estrogen

February 19, 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>

Propranolol Injection

February 19, 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 had 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>

Potassium Chloride Injection**February 19, 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>

Ondansetron Injection**February 19, 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.
- Hospira had ondansetron on shortage due to manufacturing delays.
- Mylan Institutional has new NDC numbers for ondansetron 2 mg/mL injectable products.
- Teva plans to re-launch ondansetron 20 mL injection in February 2015.
- West-Ward had ondansetron on back order due to increased demand.
- Wockhardt has ondansetron injection on shortage due to 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>

Milrinone Injection**February 19, 2015**Reason for the Shortage

- Fresenius Kabi states the reason for the shortage is increased demand for the product.
- West-Ward states the shortage is due to manufacturing delays.
- Ben Venue stopped production in its plant in Bedford, Ohio and closed in July 2014.
- Apotex, Bioniche, and Teva discontinued milrinone 1 mg/mL vials.
- Sanofi-Aventis discontinued Primacor injection.

Article Link:

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

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

Methylphenidate Hydrochloride Extended Release Oral Presentations

February 19, 2015

Reason for the Shortage

- Mallinckrodt states the shortage was due to delay in obtaining raw materials.
- Teva introduced generic methylphenidate extended release capsules (CD) in late-September 2012, and these capsules are AB-rated to Metadate CD capsules.
- 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.
- UCB states methylphenidate ER tablets were on shortage due to supply and demand.
- 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.
- Novartis discontinued Ritalin SR in October 2014.

Article Link:

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

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

Magnesium Sulfate Injection

February 19, 2015

Reason for the Shortage

- American Regent has magnesium sulfate on shortage due to manufacturing delays.
- Fresenius Kabi (formerly APP) had 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>

Doxycycline Capsules and Tablets

February 19, 2015

Reason for the Shortage

- Actavis states the reason for the shortage is supply and demand.
- Akorn acquired VersaPharm in August 2014.
- Aqua could not provide a reason for the shortage.
- Teva discontinued their doxycycline presentations in May 2013.
- Major discontinued most doxycycline presentations in February 2013. The company could not provide a reason for the discontinuation.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=977>

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

Cisatracurium Injection

February 19, 2015

Reason for the Shortage

- Sandoz could not provide a reason for the shortage.
- Nimbex injection was on shortage due to increased demand.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1072>

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

Azithromycin Injection

February 19, 2015

Reason for the Shortage

- Fresenius Kabi has 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.
- Pfizer has Zithromax injection on shortage due to increased demand.

Article Link:

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

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

Amoxicillin 875 mg Tablets

February 19, 2015

Reason for the Shortage

- Aurobindo had amoxicillin on shortage due to manufacturing delays.
- Dr Reddy's discontinued amoxicillin 875 mg tablets in June 2014.
- Ranbaxy has an FDA import ban on amoxicillin tablets.
- Sandoz cannot provide a reason for the shortage.
- West-Ward has amoxicillin on allocation due to increased demand.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1141>

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

Polymyxin B Sulfate Injection

February 20, 2015

Reason for the Shortage

- Fresenius Kabi (formerly APP) could not provide a reason for the shortage.
- Sagent suspended manufacturing of Polymyxin B sulfate injection in October, 2012.
- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired several products from Bedford Laboratories in July 2014 including polymyxin B sulfate injection. West-Ward is not actively marketing polymyxin B sulfate injection.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=974>

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

Morphine Injections

February 20, 2015

Reason for the Shortage

- Fresenius Kabi (formerly APP) states the shortage is due to a change in manufacturing sites.
- Hospira states the shortage is due to manufacturing delays.
- Hospira discontinued preservative-containing Carpuject syringes in August, 2012 and replaced them with preservative-free Carpuject syringes.
- West-Ward states the shortage was due to increased demand for product. West-Ward changed old Baxter to new West-Ward NDC codes in early 2012.
- IMS (Amphastar) discontinued morphine 1 mg/mL 10 mL Luer-lock syringes in March, 2012 due to low demand for the product.

Article Link:

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

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

Mercaptopurine Tablets

February 20, 2015

Reason for the Shortage

- Par discontinued mercaptopurine tablets in October 2014.
- Teva could not provide a reason for the shortage.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=997>

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

Lidocaine with Epinephrine Injection

February 20, 2015

Reason for the Shortage

- Hospira has lidocaine with epinephrine presentations on shortage due to manufacturing delays and increased demand.
- Fresenius Kabi (formerly APP) has Xylocaine with epinephrine presentations on shortage due to increased demand for the product.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=860>

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

Ceftriaxone Sodium Injection

February 20, 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>

Ceftazidime Injection

February 20, 2015

Reason for the Shortage

- Pfizer discontinued all of its ceftazidime injection products in late-November, 2011.
- West-Ward discontinued all of its ceftazidime injection products in January 2012.
- Hospira has ceftazidime on shortage due to manufacturing delays.
- Covis purchased all rights to Fortaz from GlaxoSmithKline. Covis began changing NDC numbers in December 2012.
- Sagent has ceftazidime injection on shortage due to increased demand for the product.
- WG Critical Care launched ceftazidime 1 gram vials in July 2013 and product is available at wholesalers. Ceftazidime 2 gram and 6 gram presentations were launched in August 2013.

Article Link:

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

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

Cefazolin Injection

February 20, 2015

Reason for the Shortage

- Fresenius Kabi, BBraun, West-Ward, and WG Critical Care have cefazolin on shortage due to increased demand.
- Apotex and Sandoz have cefazolin on shortage due to manufacturing delays.
- Hospira has cefazolin on shortage due to manufacturing delays.
- Sagent has cefazolin on shortage due to manufacturing delays.

Article Link:

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

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

Atorvastatin Tablets

February 20, 2015

Reason for the Shortage

- In November 2012, [Ranbaxy](#) voluntarily recalled 41 lots of atorvastatin tablets due to possible contamination with very small glass particles. Ranbaxy resumed supply of atorvastatin tablets in late-March 2013.
- Ranbaxy discontinued atorvastatin in late-2014.
- Apotex states the shortage is due to increased demand.
- Dr Reddy’s, Greenstone, Major, and Sandoz could not provide a reason for the shortage.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=989>

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

Adenosine Injection**February 20, 2015**Reason for the Shortage

- Astellas had Adenoscan on back order due to increased demand. This back order is now resolved. 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 manufacturing delay.
- Teva has discontinued their adenosine injection.
- 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>

Tiopronin Tablets**February 23, 2015**Reason for the Shortage

- Mission Pharmacal had Thiola on shortage due to raw materials being discontinued.
- Thiola tablets are supplied by Mission Pharmacal and distributed by Retrophin.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1067>

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

Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis (Tdap) Vaccine**February 23, 2015**Reason for the Shortage

- Sanofi-Pasteur had Adacel is in short supply due to manufacturing delays. This product is also known as adult tetanus toxoid, reduced diphtheria toxoid and acellular pertussis (Tdap) vaccine.
- Sanofi-Pasteur updated the NDC numbers on the individual vials and syringes (unit of use). The NDC numbers on the outside cartons (unit of sale) remain the same.
- GlaxoSmithKline has available Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine (Boostrix). The 1 count Boostrix syringe is no longer made.
- GlaxoSmithKline has Boostrix on shortage due to increased demand.
- Adult Tetanus and Diphtheria Toxoids Adsorbed (Td) (Tenivac, Sanofi-Pasteur) is not affected by this shortage.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1051>

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

Sumatriptan Succinate Injection

February 23, 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>

Nalbuphine Injection

February 23, 2015

Reason for the Shortage

- Endo discontinued Nubain in 2008.
- Teva discontinued all nalbuphine injections in July, 2010.
- Hospira has nalbuphine on shortage due to increased demand.

Article Link:

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

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

Methylphenidate Hydrochloride Immediate Release Tablets

February 23, 2015

Reason for the Shortage

- Mallinckrodt states the shortage was due to delay in obtaining raw materials. The company has stopped using the trade name Methylin and all products are now marketed as methylphenidate immediate-release or extended-release tablets with new NDC numbers.
- Sandoz states that the shortage is due to delay in obtaining raw materials.
- UCB states methylphenidate IR tablets were on shortage due to supply and demand.
- Actavis states the shortage of methylphenidate is due to increased demand.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1167>

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

Mesna Injection

February 23, 2015

Reason for the Shortage

- Fresenius Kabi has mesna on shortage due to increased demand.

- Mylan cannot give a reason for the shortage of mesna.
- Sagent has mesna on shortage due to increased demand.
- Teva has a shortage of mesna injection due to manufacturing delays and does not expect product until late 2015.
- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired mesna injection from Bedford in July 2014. West-Ward is not actively marketing mesna injection at this time.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1148>

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

Lidocaine Topical 4% Solution

February 23, 2015

Reason for the Shortage

- Hospira discontinued LTA Syringes kits on August 5, 2014 due to a business decision.
- Amphastar IMS has 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>

Heparin Premixed Bags

February 23, 2015

Reason for the Shortage

- Baxter and BBraun have 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>

Haloperidol Decanoate Injection

February 23, 2015

Reason for the Shortage

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

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=526>

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

Haemophilus B Conjugate Vaccine

February 23, 2015

Reason for the Shortage

- Sanofi Pasteur had ActHIB in short supply due to the shortage of other combination vaccines (eg, Pentacel®).
- GlaxoSmithKline cannot provide a reason for the shortage of Hiberix but it has not been manufactured since 2011.
- Merck discontinued Comvax vaccine in January 2015.

Article Link:

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

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

Gentamicin injection

February 23, 2015

Reason for the Shortage

- Hospira has gentamicin on shortage due to manufacturing delays
- Fresenius Kabi (formerly APP) had gentamicin on shortage due to increased demand. Fresenius Kabi discontinued their 10 mg/mL 2 mL multi-dose vial in mid-2011.
- Baxter has gentamicin on shortage due to increased demand

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=728>

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

Furosemide Injection

February 24, 2015

Reason for the Shortage

- Fresenius Kabi (formerly APP) has furosemide injection on shortage due to increased demand for the product.
- American Regent has furosemide injection on shortage due to manufacturing delays.
- Hospira states the shortage was due to manufacturing delays.
- 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>

Doxorubicin Liposomal Injection

February 23, 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.
- Janssen is working to transition Doxil manufacturing to additional suppliers. A temporary solution to this shortage was to use areas of the Ben Venue Laboratories facility available for production and other partners to complete the manufacturing

process. FDA exercised regulatory discretion and approved an additional lot of 2 mg/mL 10 mL (20 mg) vials.

- Ben Venue has stopped production in its plant in Bedford, Ohio and will close in early 2014. Ben Venue supplies multiple sterile injectable products for Bedford Laboratories. Supplies of product that has already been manufactured will continue to be released until inventory is depleted. Bedford Laboratories has a small number of products manufactured elsewhere that are not affected by this closure.
- 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 the market with their presentations.

Article Link:

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

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

Caffeine Citrate Injection and Oral Solution

February 23, 2015

Reason for the Shortage

- American Regent has caffeine citrate on shortage due to manufacturing delays.
- Caraco cannot provide a reason for the shortage.
- 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>

Bacitracin Topical Ointment

February 23, 2015

Reason for the Shortage

- Altaire, Sandoz, and Qualitest cannot provide a reason for the shortage.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=677>

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

Atracurium Injection

February 23, 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 had atracurium on shortage due to manufacturing delays.
- Sagent has atracurium on shortage due to manufacturing delays.

Article Link:

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

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

Atenolol Tablets**February 23, 2015**Reason for the Shortage

- AstraZeneca divested Tenormin to Almatica in January 2015.
- 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>

Anagrelide Capsules**February 23, 2015**Reason for the Shortage

- Mylan and Teva cannot provide a reason for the shortage.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1156>

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

Ammonium Molybdate Injection**February 23, 2015**Reason for the Shortage

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

Article Link:

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

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

Acetylcysteine Inhalation Solution**February 23, 2015**Reason for the Shortage

- American Regent has acetylcysteine inhalation on shortage due to manufacturing delays.
- Roxane Labs discontinued acetylcysteine inhalation solution in April 2014. The product had previously been on shortage due to manufacturing delays.
- Hospira has acetylcysteine inhalation solution on shortage due to manufacturing delay.

- Fresenius Kabi (formerly APP) states the reason for the shortage is increased demand.

Article Link:

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

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

Sodium Chloride 0.9% Injection Bags

February 24, 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 imported 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 Spain by Baxter.

Article Link:

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

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

Ketorolac Tromethamine Injection

February 24, 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.

Article Link:

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

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

Esmolol Injection

February 24, 2015

Reason for the Shortage

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

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=833>

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

Dexamethasone Sodium Phosphate

February 24, 2015

Reason for the Shortage

- American Regent has dexamethasone sodium phosphate on shortage due to manufacturing delays.
- Fresenius Kabi states the dexamethasone sodium phosphate shortage is due to supply and demand issues.
- Baxter could not provide a reason for the shortage. Baxter sold several products to West-Ward in mid-2011.
- West-Ward had dexamethasone sodium phosphate injection on shortage due to increased demand.
- Pfizer divested all dexamethasone presentation to Mylan Institutional on December 6, 2013.
- Mylan Institutional states the shortage is due to increased demand.

Article Link:

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

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

Deferoxamine Mesylate Injection

February 24, 2015

Reason for the Shortage

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

Article Link:

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

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

Bupivacaine Injection

February 24, 2015

Reason for the Shortage

- Fresenius Kabi (formerly APP) 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>

Paclitaxel Injection

February 25, 2015]

Reason for the Shortage

- Fresenius Kabi (formerly APP) had paclitaxel on shortage due to increase demand for the product.¹
- West-Ward Pharmaceuticals’ parent company, Hikma Pharmaceuticals, acquired paclitaxel injection from Bedford in July 2014. West-Ward is not actively marketing paclitaxel.^{2,3}
- Teva has paclitaxel on shortage due to manufacturing delays.⁴
- Sandoz has paclitaxel on back order due to a raw material shortage.⁵
- Hospira had paclitaxel on shortage due to increased demand.^{6,7}
- Sagent has paclitaxel on shortage due to increased demand.⁸
- Sagent discontinued paclitaxel 30 mg/5 mL and 100 mg/16.7 mL presentations in October 2014.⁸
- Pfizer launched paclitaxel 100 mg and 300 mg vials in March, 2012 and launched the 30 mg vials in April, 2012.⁹
- Mylan Institutional acquired paclitaxel injection from Pfizer on December 7, 2013.^{9,10}
- WG Critical Care launched paclitaxel injection in September 2014.¹¹

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=790>

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

Leuprolide Acetate 14-Day Kit

February 25, 2015

Reason for the Shortage

- Caraco could not provide a reason for the shortage.
- 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>

Divalproex Sodium Delayed Release Tablets

February 25, 2015

Reason for the Shortage

- Caraco, Teva, Mylan, and Unichem Laboratories cannot provide a 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>

* Please refer to ASHP website for more information

NEW DRUGS COMING TO MARKET

PRODUCT	MFR	ROUTE	INDICATION	PHARMACOLOGY	MARKET RELEASE
Empagliflozin and linagliptin	Boehringer Ingelheim/ Eli Lilly	PO	Type II diabetes	Sodium-glucose cotransporter-2 (SGLT2) inhibitor and DPP-4 inhibitor	NDA filed 4/2014
Toujeo	Sanofi	INJ (SC)	Type I and II diabetes	Long acting U300 basal insulin	NDA filed 7/2014
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
Veruprevir (ABT-450)/ Ombitasvir (ABT-267)/ Dasabuvir (ABT-333)	AbbVie	PO	Hepatitis C	Hepatitis C virus NS3/4A protease inhibitor (given with ritonavir as booster)/NS5A inhibitor combination given with NS5B polymerase inhibitor dasabuvir	All oral triple therapy receives FDA breakthrough therapy designation 5/2013; NDA filed 4/22/2014; FDA action expected 12/2014
Darunavir and cobicistat	Gilead	PO	HIV	Protease inhibitor and pharmacokinetic enhancer	NDA filed 4/2014
Isavuconazole	Basilea	PO,IV	Treatment of systemic and invasive Candida and Aspergillus infections	Binds and inhibits ergosterol synthesis by inhibiting CYP450-dependent 14-alpha sterol demethylase	Orphan drug status; QIDP designation for Aspergillois 12/2013; NDA filed 7/2014; FDA action expected

PRODUCT	MFR	ROUTE	INDICATION	PHARMACOLOGY	MARKET RELEASE
					3/2015
Avibactam/ ceftazidime	Astra/Zen	IV	Gram negative infections	Combination of novel β -lactamase inhibitor and broad-spectrum cephalosporin	QIDP designation 9/2013; NDA filed; FDA action expected 1Q2015
Panobinostat (Faridak; LBH-589)	Novartis	PO	Cutaneous T-cell lymphoma, CML, MDS	Novel and highly potent histone deacetylase (HDAC) inhibitor that induces cell death of tumor cell lines but not normal cells	NDA filed 3-2014; FDA priority review with action date 11-2014, FDA advisory committee voted 5-2 against approval 11/2014; FDA action expected 2/2015
Palbociclib	Pfizer	PO	Breast cancer	Blocks cyclin dependent kinases (CDK) 4 and 6	FDA Breakthrough Designation 10/2014; FDA action date 4/2015
Lenvatinib	Eisai	PO	Thyroid cancer	Multi-receptor tyrosine kinase inhibitor that inhibits RET kinase and vascular endothelial growth factor receptor (VEGFR)	NDA filed 10-2014; FDA orphan drug status; FDA priority review; FDA action date 4/2015
Sonidegib (LDE-225)	Novartis	PO	Basal cell carcinoma	Smoothend (Smo) antagonist; Hedgehog (Hh) signaling pathway inhibitor	NDA filed 10/2014
Ivabradine	Amgen/ Servier	PO	Chronic heart failure	Bradycardic agent with action on the sino-atrial node	NDA filed 6/2014; FDA fast-track and

PRODUCT	MFR	ROUTE	INDICATION	PHARMACOLOGY	MARKET RELEASE
				controlled by the If current	priority review with action 2/2015
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
Donepezil HCl/ memantine Er (Arimenda)	Adamas	PO	Alzheimer's disease	Fixed dose combination of NMDA receptor antagonist and an acetylcholine- esterase inhibitor	NDA filed 3/2014
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
Naloxegol (Movantik)	Nektar/ AstraZen	PO	Opioid-induced constipation	PEGylated tablet formulation of naloxol (an analogue of naloxone)	FDA approved 9/2014; Launch planned for 1Q2015
Eluxadoline (JNJ- 27018966)	Janssen/ Furiex	PO	Irritable bowel syndrome	Opioid delta receptor antagonists; opiod mu receptor agonists	NDA filed 9/2014; FDA priority review
Rolapitant	TESARO/ OPKO Health	PO	Chemotherapy induced nausea and vomiting (prevention)	Neurokinin 1 receptor antagonists	NDA filed 9/2014
Secukinumab (AIN-457)	Novartis	INJ (SC and IV)	Psoriatic arthritis, plaque psoriasis)	Fully human monoclonal antibody targeting interleukin-17 (IL- 17)	BLA filed 10/2013; FDA approved 1/2015
Drisapersen	Prosensa	INJ (SC)	Duchenne Muscular Dystrophy	Antisense nucleotide that induced specific	Phase III; FDA breakthrough therapy

PRODUCT	MFR	ROUTE	INDICATION	PHARMACOLOGY	MARKET RELEASE
				skipping of exon 51 during splicing	designation granted 6/2013; Rolling NDA initiated 10/2014
Albuterol multi-dose dry powder inhaler (Spiromax)	Teva	INH	Reversible obstructive airway disease	Albuterol multi-dose dry powder inhaler (MDPI)	NDA filed 7/2014
Olodaterol/tiotropium	Boehringer Ingelheim	INH	COPD	Fixed-dose LABA/LAMA combination with Respimat inhaler	NDA filed 8/2014
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
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
Zarzio (Filgrastim biosimilar)	Sandoz	INJ (SC)	Neutropenia	Neupogen biosimilar	BLA submitted 7-2014 (biosimilar pathway); FDA action as early as 3/2015
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	NDA filed 10/2014

PRODUCT	MFR	ROUTE	INDICATION	PHARMACOLOGY	MARKET RELEASE
				as patiomer, a potassium binder	
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
Multicomponent meningococcal serogroup B vaccine (4CMenB or Bexsero)	Novartis	INJ (IM)	Prevention of meningitis B	Produced using reverse vaccinology, which decodes genetic makeup of MenB & selects proteins that are most likely to be protective vaccine candidates	FDA breakthrough therapy designation; NDA filed 6/2014; FDA approved 1/2015