March 2015*

Drug Information Update

*Includes drug information from February - March 2015

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NEW GENERICS TO MARKET

GENERIC DRUG NAME	STRENGTH & DOSAGE FORM	GENERIC MANUFACTURER	BRAND NAME	APPROVAL DATE
PROPARACAINE/FLUORESCEIN SOD	0.5%-0.25% DROPS	Altaire Pharmaceuticals	FLUCAINE	12/18/2003
PRAMIPEXOLE DI-HCL	1.5 MG TAB ER 24 HR	PAR Pharmaceuticals	MIRAPEX ER	02/10/2015
PRAMIPEXOLE DI-HCL	0.75 MG TAB ER 24 HR	Boehringer Ing.	MIRAPEX ER	11/15/2010
TRANDOLAPRIL/VERAPAMIL HCL	2-180MG TBMP 24 HR	Greenstone LLC	TARKA	2/25/2015
TRANDOLAPRIL/VERAPAMIL HCL	4-240MG TBMP 24 HR	Greenstone LLC	TARKA	2/25/2015
TRANDOLAPRIL/VERAPAMIL HCL	2-240MG TBMP 24 HR	Greenstone LLC	TARKA	2/25/2015
TRANDOLAPRIL/VERAPAMIL HCL	1-240MG TBMP 24 HR	Greenstone LLC	TARKA	2/25/2015
METHYLPHENIDATE HCL	5 MG TAB CHEW	Gavis Pharmaceutical	METHYLIN	3/9/2015
METHYLPHENIDATE HCL	10 MG TAB CHEW	Gavis Pharmaceutical	METHYLIN	3/9/2015
METHYLPHENIDATE HCL	2.5 MG TAB CHEW	Gavis Pharmaceutical	METHYLIN	3/9/2015
NAPROXEN SODIUM	500 MG TBMP 24 HR	Alvogen Inc	NAPRELAN CR	3/11/2015
OM-3/DHA/EPA/D3/B12/FA/B-6/PHY	500 mg-350 mg-35 mg-1,000 unit-500 mcg-1 mg-12.5 mg-200 mg CAPS	Accella Pharmaceutical	ANIMI-3	3/19/2015
BENZOYL PEROXIDE MICROSPHERES	7% CLEANSER	Prugen Pharmaceutical	BENZEPRO	2/27/2015
ESOMEPRAZOLE MAGNESIUM	40 MG CAPSULE DR	TEVA USA	NEXIUM	2/17/2015
ESOMEPRAZOLE MAGNESIUM	20 MG CAPSULE DR	TEVA USA	NEXIUM	2/17/2015
NEOSTIGMINE METHYLSULFATE	0.5 MG/ML VIAL	APP Pharmaceutical	BLOXIVERZ	2/18/2015
NEOSTIGMINE METHYLSULFATE	1 MG/ML VIAL	APP Pharmaceutical	BLOXIVERZ	2/18/2015
POLYDIMETHYLSILOXANES/SILICON	GEL (GRAM)	Exeltis USA Der	RECEDO	03/26/2015

NEW DRUG ENTITIES

DESCRIPTION	BRAND NAME	GENERIC NAME	STRENGTH	NOTES
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
ANALGESICS, NARCOTICS	FENTANYL	FENTANYL	37.5MCG/HR	New Strength
ANALGESICS, NARCOTICS	FENTANYL	FENTANYL	87.5MCG/HR	New Strength
ANALGESICS, NARCOTICS	FENTANYL	FENTANYL	62.5MCG/HR	New Strength
TOPICAL SULFONAMIDES	ROSULA	SULFACETAMIDE SODIUM/SULFUR	10 %-4.5 %	New Strength
ANTINEOPLASTICS, MISCELLANEOUS	DOCETAXEL	DOCETAXEL	200MG/20 ML	New Strength
INFANT FORMULAS	ENFAMIL HUMAN MILK FORTIFIER	INFANT FORM.IRON,HUMAN MILK FT	0.55 G/5ML	New Combination
ANDROGENIC AGENTS	NATESTO	TESTOSTERONE	5.5/0.122	New Route
ANALGESICS, NARCOTICS	ZOHYDRO ER	HYDROCODONE BITARTRATE	10 MG	New Formulation.
ANALGESICS, NARCOTICS	ZOHYDRO ER	HYDROCODONE BITARTRATE	15 MG	New Formulation.
ANALGESICS, NARCOTICS	ZOHYDRO ER	HYDROCODONE BITARTRATE	20 MG	New Formulation.
ANALGESICS, NARCOTICS	ZOHYDRO ER	HYDROCODONE BITARTRATE	30 MG	New Formulation.
ANALGESICS, NARCOTICS	ZOHYDRO ER	HYDROCODONE BITARTRATE	40 MG	New Formulation.
ANALGESICS, NARCOTICS	ZOHYDRO ER	HYDROCODONE BITARTRATE	50 MG	New Formulation.
ANTIHEMOPHILIC FACTORS	NOVOEIGHT	ANTIHEMOPH.FVIII,B-DOM TRUNCAT	250 (+/-)	New Entity
ANTIHEMOPHILIC FACTORS	NOVOEIGHT	ANTIHEMOPH.FVIII,B-DOM TRUNCAT	500 (+/-)	New Entity

DESCRIPTION	BRAND NAME	GENERIC NAME	STRENGTH	NOTES
ANTIHEMOPHILIC FACTORS	NOVOEIGHT	ANTIHEMOPH.FVIII,B-DOM TRUNCAT	1000 (+/-)	New Entity
ANTIHEMOPHILIC FACTORS	NOVOEIGHT	ANTIHEMOPH.FVIII,B-DOM TRUNCAT	1500 (+/-)	New Entity
ANTIHEMOPHILIC FACTORS	NOVOEIGHT	ANTIHEMOPH.FVIII,B-DOM TRUNCAT	2000 (+/-)	New Entity
ANTIHEMOPHILIC FACTORS	NOVOEIGHT	ANTIHEMOPH.FVIII,B-DOM TRUNCAT	3000 (+/-)	New Entity
CYSTIC FIB-TRANSMEMB CONDUCT.REG.(CFTR)POTENTIATOR	KALYDECO	IVACAFTOR	50 MG	New Strength and Dosage Form
CYSTIC FIB-TRANSMEMB CONDUCT.REG.(CFTR)POTENTIATOR	KALYDECO	IVACAFTOR	75 MG	New Strength and Dosage Form
INSULINS	TOUJEO SOLOSTAR	INSULIN GLARGINE,HUM.REC.ANLOG	300/ML	New Entity
VAGINAL ANTIBIOTICS	NUVESSA	METRONIDAZOLE	1.3 %	New Strength
ANTINEOPLAST,HISTONE DEACETYLASE (HDAC) INHIBITORS	FARYDAK	PANOBINOSTAT LACTATE	20 MG	New Entity
ANTINEOPLAST,HISTONE DEACETYLASE (HDAC) INHIBITORS	FARYDAK	PANOBINOSTAT LACTATE	15 MG	New Entity
ANTINEOPLAST,HISTONE DEACETYLASE (HDAC) INHIBITORS	FARYDAK	PANOBINOSTAT LACTATE	10 MG	New Entity
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
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	LENVIMA	LENVATINIB MESYLATE	14 MG/DAY	New Entity

DESCRIPTION	BRAND NAME	GENERIC NAME	STRENGTH	NOTES
INHIBITORS				
ANTINEOPLASTIC SYSTEMIC ENZYME INHIBITORS	LENVIMA	LENVATINIB MESYLATE	10 MG/DAY	New Entity
ANTINEOPLASTIC SYSTEMIC ENZYME INHIBITORS	LENVIMA	LENVATINIB MESYLATE	20 MG/DAY	New Entity

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 fliptop 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

Atracurium Besylate Injection by Sagent Pharmaceuticals: Recall - Potential Impact on Product Sterility

[Posted 02/24/2015]

ISSUE: Sagent Pharmaceuticals, Inc. announced the voluntary nationwide recall of two lots of Atracurium Besylate Injection, USP, 50mg/5mL single-dose vials (NDC 25021-659-05) and four lots of Atracurium Besylate Injection, USP, 100mg/10mL multi-dose vials (NDC 25021-672-10) manufactured by Emcure Pharmaceuticals Ltd. and distributed by Sagent. Sagent has initiated this voluntary recall of Atracurium Besylate Injection, USP, 50mg/5mL and 100mg/10mL to the user level due to FDA observations pertaining to aseptic and GMP practices at the manufacturer's site potentially impacting product sterility.

Non-sterility of a drug administered via the intravenous route has the potential to result in infections, which could be fatal, especially in patients who are immunocompromised.

BACKGROUND: The lot numbers being recalled are VATA012, VATA015 (50mg/5mL) and VATB012, VATB013, VATB014, VATB017 (100mg/10mL) which were distributed to hospitals, wholesalers and distributors nationwide from February 2014 through February 2015 and are supplied in single-dose and multi-dose vials.

Sagent has transferred the manufacture of this product to its own facility and this product manufactured at the Sagent facility will not be impacted by the recall.

RECOMMENDATION: Customers are instructed to examine their inventory immediately and to quarantine, discontinue distribution of and return the recalled lots of product. Customers who may have further distributed this product have been requested to identify their customers and notify them at once of this product recall. The necessary form by which to document this information as well as other information regarding this recall is available at www.Sagentpharma.com. Customers are being notified by fax, email, FedEx, and/or certified mail that includes arrangements for return of all recalled product. Any questions about returning unused product should be directed to the customer call center at (866) 625-1618 M-F 8am-7pm CST. Healthcare workers who have medical questions about Atracurium Besylate Injection, USP may contact Sagent Medical Affairs (866-625-1618, Option 3) M-F 8am-5pm CST.
Source: U.S. Food and Drug Administration (FDA)
Article link:
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm435440.htm

Colistimethate for Injection USP, 150 mg and Rifampin for Injection USP, 600 mg/vial by Heritage Pharmaceuticals: Recall - Lack of Sterility Assurance

[Posted 02/25/2015]

ISSUE: Heritage Pharmaceuticals Inc. announced the voluntary nationwide recall of ten (10) lots of Colistimethate for Injection, USP, 150 mg Single-Dose vial (NDC 23155-193-31) and three (3) lots of Rifampin for Injection, USP, 600 mg Single-Dose vial (NDC 23155-340-31) manufactured by Emcure Pharmaceuticals Ltd. and distributed by Heritage. Heritage has initiated this voluntary recall to the user level due to FDA observations pertaining to aseptic and GMP practices at the manufacturer's site potentially impacting product sterility. See the Press Release for a listing of affected lot numbers.

Intravenous administration of non-sterile injection products to a normally sterile site may result in a site-specific or systemic infection, which in turn may cause hospitalization, significant morbidity (permanent organ damage), or fatal outcome. To date, Heritage is not aware of any adverse patient events resulting from the use of the subject product lots.

BACKGROUND: The products were distributed to hospitals, wholesalers and distributors nationwide from December 2012 through January 2015 (Colistimethate) and from October 2014 through January 2015 (Rifampin). Colistimethate is indicated for the treatment of acute or chronic infections due to sensitive strains of certain gram-negative bacteria. Rifampin is indicated for the treatment of all forms of tuberculosis.

RECOMMENDATION: Customers are being notified by fax, email, UPS, and/or certified mail that includes arrangements for return of all recalled product. Customers have been instructed to examine their inventory immediately and to quarantine, discontinue distribution of, and return the recalled lots of product. Customers who may have further distributed these products have been requested to identify their customers and notify them at once of this product recall.

Any questions about returning unused product should be directed to the customer call center at (866) 901-1230 M-F 9am-5pm EST. Healthcare workers who have medical questions about Colistimethate for Injection, USP, 150 mg base/vial and Rifampin for Injection USP, 600 mg/vial may contact Heritage Medical Affairs (732-429-1000, Ext. 101) M-F 9am-5pm EST. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this product.
Source: U.S. Food and Drug Administration (FDA)
Article link:
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm435616.htm

Testosterone Products: Drug Safety Communication - FDA Cautions About Using Testosterone Products for Low Testosterone Due to Aging; Requires Labeling Change to Inform of Possible Increased Risk of Heart Attack And Stroke

[Posted 03/03/2015]

ISSUE: FDA is requiring that the manufacturers of all approved prescription testosterone products change their labeling to clarify the approved uses of these medications. FDA is also requiring these manufacturers to add information to the labeling about a possible increased risk of heart attacks and strokes in patients taking testosterone. FDA cautions that prescription testosterone products are approved only for men who have low testosterone levels caused by certain medical conditions. The benefit and safety of these medications have not been established for the treatment of low testosterone levels due to aging, even if a man's symptoms seem related to low testosterone.

Based on the available evidence from studies and expert input from an FDA Advisory Committee meeting, FDA has concluded that there is a possible increased cardiovascular risk associated with testosterone use. These studies included aging men treated with testosterone. Some studies reported an increased risk of heart attack, stroke, or death associated with testosterone treatment, while others did not. See the Data Summary section of the FDA Drug Safety Communication for additional details.

BACKGROUND: Testosterone is FDA-approved as replacement therapy only for men who have low testosterone levels due to disorders of the testicles, pituitary gland, or brain that cause hypogonadism. However, FDA has become aware that testosterone is being used extensively in attempts to relieve symptoms in men who have low testosterone for no apparent reason other than aging. The benefits and safety of this use have not been established.

RECOMMENDATION: Health care professionals should prescribe testosterone therapy only for men with low testosterone levels caused by certain medical conditions and confirmed by laboratory tests. Health care professionals should make patients aware of the possible increased cardiovascular risk when deciding whether to start or continue a patient on testosterone therapy. Patients using testosterone should seek medical attention immediately if symptoms of a heart attack or stroke are present, such as chest pain, shortness of breath or trouble breathing, weakness in one part or one side of the body, or slurred speech.
Source: U.S. Food and Drug Administration (FDA)
Article link:
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm436280.htm

Magnesium Sulfate in 5 Percent Dextrose Injection by Hospira: Recall - Incorrect Barcode Labeling

[Posted 03/06/2015]

ISSUE: Hospira announced a voluntary recall of one lot of Magnesium Sulfate in 5% Dextrose, Inj., USP, 10 mg/mL (NDC: 0409-6727-23, Lot 42-120-JT, Expiry 1DEC2015) to the user level due to confirmed customer reports of an incorrect barcode on the primary bag labeling. The barcode on the overwrap is correct; however, there is potential for the primary container barcode to be mislabeled with the barcode for Heparin Sodium 2000 USP units/1000 mL in 0.9% Sodium Chloride Inj. The product is labeled with the correct printed name on the primary container and overwrap.

If the incorrect barcode on Magnesium Sulfate in 5% Dextrose, Inj., USP, 10 mg/ mL is not detected prior to dispensing or administration to a patient, and the product is administered based on the printed name, patient harm is unlikely since the barcode on the overwrap and readable text on the primary container and overwrap are correct. However, if detected, there is the potential for delay in treatment of magnesium sulfate in 5% dextrose, that can result in life-threatening seizures, stroke, cerebral hemorrhage and maternal death, and attendant risks to the fetus, including fetal demise. Administration of the magnesium sulfate drug product to a patient who is prescribed heparin and in whom the magnesium sulfate is contraindicated can result in serious adverse events related to the drug's pharmacologic action and may require medical intervention.

BACKGROUND: Magnesium sulfate in 5% dextrose injection, USP, is a prescription product administered intravenously for the prevention and control of seizures in preeclampsia and eclampsia, respectively. The product is packaged in 50/100 mL container bags and sold 24 bags per carton (NDC: 0409-6727-23, Lot 42-120-JT, Expiry 1DEC2015). The lot was distributed nationwide in the U.S. to wholesalers, distributers and hospitals from October 2014 to January 2015.

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 will be notifying its direct customers via a recall letter and is arranging for impacted product to be returned to Stericycle in the United States. For additional assistance, call Stericycle at 1-866-382-9260 between the hours of 8 a.m. to 5 p.m. ET, Monday through Friday. Patients should contact their physician or healthcare provider if they have experienced any problems that may be related to using this drug product.
Source: U.S. Food and Drug Administration (FDA)
Article link:

http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm437113.htm

0.9 Percent Sodium Chloride Injection, USP, 250 mL VisIV Container by Hospira: Recall - Particulate Matter

[Posted 03/06/2015]

ISSUE: Hospira announced a voluntary nationwide recall of one lot of 0.9% Sodium Chloride Injection, USP, 250 mL VisIV flex container (NDC 0409-7983-25, Lot 45-110-C6, Expiry 1MAR2016) to the user level due to one confirmed customer report of particulate in a single unit. The foreign particle was confirmed by Hospira as human hair free-floating within the solution. To date, Hospira has not received reports of any adverse events associated with this issue for this lot.

Injected particulate material may result in localized inflammation, phlebitis, allergic reaction, granuloma formation or microembolic effects (IV only) 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: This lot was distributed nationwide from December 2014 through January 2015. 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 will be notifying its direct customers via a recall letter and is arranging for impacted product to be returned to Stericycle in the United States. For additional assistance, call Stericycle at 1-888-714-5079 between the hours of 8 a.m. to 5 p.m. ET, Monday through Friday.

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

Article link:

http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm436871.htm

Chantix (varenicline): Drug Safety Communication - FDA Updates Label to Include Potential Alcohol Interaction

[Posted 03/09/2015]

ISSUE: FDA is warning that the prescription smoking cessation medicine Chantix (varenicline) can change the way people react to alcohol. Interactions between alcohol and Chantix have resulted in some patients experiencing increased intoxicating effects of alcohol, sometimes associated with aggressive behavior and/or amnesia. In addition, rare accounts of seizures in patients treated with Chantix have been reported. FDA has approved changes to the Chantix label to warn about these risks. Refer to the Drug Safety Communication for a detailed data summary.

BACKGROUND: Chantix is a prescription medicine that is FDA-approved to help adults quit smoking.

RECOMMENDATION: Healthcare professionals should weigh the potential risk of seizures against the potential benefits before prescribing Chantix in patients with a history of seizures or other factors that can lower the seizure threshold. Advise patients to immediately stop taking Chantix if they develop agitation, hostility, aggressive behavior, depressed mood, or changes in behavior or thinking that are not typical for them, or if they develop suicidal ideation or behavior.
Until patients know how Chantix affects their ability to tolerate alcohol, they should decrease the amount of alcohol they drink. Patients who have a seizure while taking Chantix should stop the medicine and seek medical attention immediately.
Source: U.S. Food and Drug Administration (FDA)
Article link:
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm437415.htm

Treanda (bendamustine hydrochloride) Solution by Teva: FDA Statement - Not Compatible with Closed System Transfer Devices, Adapters, and Syringes Containing Polycarbonate or Acrylonitrile-Butadiene-Styrene

[Posted 03/10/2015]

ISSUE: FDA is warning health care professionals not to use Treanda Injection (45 mg/0.5 mL or 180 mg/2 mL solution) with closed system transfer devices (CSTD), adapters, and syringes containing polycarbonate or acrylonitrile-butadiene-styrene (ABS). Most marketed CSTDs contain either polycarbonate or ABS and are not compatible with Treanda Injection (45 mg/0.5 mL or 180 mg/2 mL solution). N, N-dimethylacetamide (DMA), an ingredient in Treanda Injection (45 mg/0.5 mL or 180 mg/2 mL solution), is incompatible with polycarbonate or ABS. Devices that contain polycarbonate or ABS dissolve when coming into contact with DMA. This can lead to device failure, possible product contamination, and potential serious adverse health consequences, including skin reactions in health care professionals preparing and

administering this product and the risk of small blood vessel blockage in patients. FDA is requiring label changes for both the solution and the powder formulations of Treanda to reflect safe preparation information.

BACKGROUND: Treanda is available in two formulations, a solution, Treanda Injection (45 mg/0.5 mL or 180 mg/2 mL solution); and a lyophilized powder, Treanda for Injection (25mg/vial or 100 mg/vial lyophilized powder). Closed system transfer devices are devices that are used to prepare and administer hazardous drugs for intravenous infusion, such as chemotherapy drugs.

RECOMMENDATION: Health care professionals should stop using Treanda Injection (45 mg/0.5 mL or 180 mg/2 mL solution) with CSTDs or vial adapters and syringes containing polycarbonate or ABS. If using Treanda Injection (45 mg/0.5 mL or 180 mg/2 mL solution):

- If a CSTD would be used with Treanda Injection (45 mg/0.5 mL or 180 mg/2 mLsolution), FDA advises health care professionals to verify with the CSTD manufacturer or Teva U.S. Medical Information (1-800-896-5855) that the CSTD is compatible with Treanda Injection (45 mg/0.5 mL or 180 mg/2 mL solution) prior to preparing the drug.
- FDA recommends health care professionals only use a polypropylene syringe with a metal needle and polypropylene hub to withdraw and transfer Treanda Injection. Polypropylene syringes are translucent in appearance.
- Treanda Injection (45 mg/0.5 mL or 180 mg/2 mL solution) should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit.
- Treanda Injection (45 mg/0.5 mL or 180 mg/2 mL solution) must be withdrawn and transferred for dilution in a biosafety cabinet (BSC) or containment isolator and withdrawn and transferred using a polypropylene syringe with a metal needle and a polypropylene hub.

If using Treanda for Injection (25mg/vial or 100 mg/vial lyophilized powder):

- Treanda for Injection (25mg/vial or 100 mg/vial lyophilized powder), must be reconstituted. If a CTSD or adaptor is to be used as supplemental protection during preparation, only use Treanda for Injection (25mg/vial or 100 mg/vial lyophilized powder) and not the solution formulation.
- Do not mix or combine the solution and lyophilized powder formulations of Treanda.

Source: U.S. Food and Drug Administration (FDA)
Article link:
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm437626.htm

Lactated Ringer's Irrigation, 3000mL by Hospira: Recall - Mold Contamination

[Posted 03/12/2015]

ISSUE: Hospira initiated a voluntary recall of one lot of Lactated Ringer's Irrigation, 3000mL (NDC 0409-7828-08, Lot 40-008-JT; Expiry 1APR2016) to the user level (both human and veterinary) due to a confirmed customer report of several dark, fibrous particulates floating within the solution of the primary container. The particulate was confirmed as a common non-toxic, non-invasive mold, Aspergillus kanagawaensis. If contaminated solution is used on a patient it may cause bacteremia, sepsis, septic shock and endocarditis, and death may result. Signs and symptoms may include redness, pain, swelling at the site, fever, shortness of breath, tachycardia, nausea, and vomiting. Septicemia could lead to shock and multi-system organ failure, requiring critical medical intervention. The mold is considered allergenic and exposure to it may induce an allergic response or immune response to the particulate including anaphylaxis. Delayed therapy may occur if the particulate were to block the flow of the solution during irrigation.

BACKGROUND: Lactated Ringers Irrigation is a sterile, nonpyrogenic solution of electrolytes in water for injection, intended only for sterile irrigation, washing and rinsing purposes. The product is packaged in 3000 mL flexible container bags and sold four bags per carton (NDC: 0409-7828-08, Lot 40-008-JT, Expiry 1APR2016). The lot was distributed nationwide in the United States to wholesalers, distributors, surgery centers, and hospitals from June 2014 through September 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 user level (both human and veterinary). Hospira will be notifying its direct customers via a recall letter and is arranging for impacted product to be returned to Stericycle in the United States. For additional assistance, call Stericycle at 1-877-907-7037 between the hours of 8 am to 5 pm ET, Monday through Friday.

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

Article link:

http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm437818.htm

Over-the-Counter Asthma Products Labeled as Homeopathic: FDA Statement - Consumer Warning About Potential Health Risks

[Posted 03/19/2015]

ISSUE: FDA is warning consumers not to rely on asthma products labeled as homeopathic that are sold over-the-counter (OTC). These products have not been evaluated by the FDA for safety and effectiveness. Asthma is a serious, chronic lung condition. If asthma is not appropriately treated and managed, patients may have wheezing, shortness of breath, and coughing, and could be at risk for life-threatening asthma attacks that may require emergency care or hospitalization. Although there is no cure for asthma, there are many prescription asthma treatments approved by FDA as safe and effective, as well as some products that are marketed OTC in accordance with an FDA monograph.

BACKGROUND: OTC asthma products labeled as homeopathic are widely distributed through retail stores and via the internet. Many of these products are promoted as "natural," "safe and effective," and include indications that range from treatment for acute asthma symptoms, to temporary relief of minor asthma symptoms. In general, consumers can identify such products by looking for the word "HOMEOPATHIC" or "HOMŒOPATHIC" on a product's label and looking for whether the product's active ingredient(s) are listed in terms of dilution (e.g., "LM1" "6X" or "30C").

RECOMMENDATION: Speak to your health care provider if you think you or your child may have asthma. Consumers with asthma can take an active role in managing their condition by making certain they have appropriate treatments on hand in the event they experience an asthma attack or a worsening of asthma symptoms, and by consulting with a health care provider when needed.
Source: U.S. Food and Drug Administration (FDA)
Article link:
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm439014.htm

Zyprexa Relprevv (olanzapine pamoate): Drug Safety Communication - FDA Review of Study Sheds Light on Two Deaths Associated with the Injectable Schizophrenia Drug

[Posted 03/23/2015]

ISSUE: FDA has concluded a review of a study undertaken to determine the cause of elevated levels of the injectable schizophrenia drug Zyprexa Relprevv (olanzapine pamoate) in two patients who died. The study results were inconclusive. FDA is unable to exclude the possibility that the deaths were caused by rapid, but delayed, entry of the drug into the bloodstream following intramuscular injection. The study suggested that much of the drug level increase could have occurred after death, a finding that could explain the extremely high blood levels found in the two patients who died 3 to 4 days after receiving injections of appropriate doses of Zyprexa Relprevv. On the basis of all of the information reviewed (refer to the Drug Safety

Communication for a full data summary), FDA is not recommending any changes to the current prescribing or use of Zyprexa Relprevv injection at this time. Patients should not stop receiving treatment without first talking to their health care professionals.

BACKGROUND: Treatment with Zyprexa Relprevv may help improve the symptoms of schizophrenia, which include hearing voices, seeing things that are not there, and being suspicious or withdrawn. The labeling for Zyprexa Relprevv carries a boxed warning, FDA's most serious type of warning, for post-injection delirium sedation (PDSS). This is an update to the MedWatch safety alert issued on June 18, 2013.

RECOMMENDATION: Patients should read the Medication Guide that comes with the Zyprexa Relprevv prescription each time before they get an intramuscular injection, as there may be new information. Patients receiving Zyprexa Relprevv or their caregivers should immediately report symptoms of PDSS to a health care professional. Health care professionals should continue to follow the Zyprexa Relprevv Patient Care Program Risk Evaluation and Mitigation Strategy (REMS) requirements and current label recommendations. Notable requirements of the REMS include:

- For a patient to receive treatment, the prescriber, health care facility, patient, and pharmacy must all be enrolled in the Zyprexa Relprevv Patient Care Program.
- Zyprexa Relprevv injections must be administered at a REMS-certified health care facility with ready access to emergency response services.
- Patients must be continuously monitored at the REMS-certified health care facility for at least 3 hours following an intramuscular injection.
- Patients receiving Zyprexa Relprevv must be accompanied to their destination from the health care facility.

Source: U.S. Food and Drug Administration (FDA)
Article link:
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm439472.htm

Hepatitis C Treatments Containing Sofosbuvir in Combination With Another Direct Acting Antiviral Drug: Drug Safety Communication - Serious Slowing of Heart Rate When Used With Antiarrhythmic Drug Amiodarone

[Posted 03/24/2015]

ISSUE: FDA is warning that serious slowing of the heart rate can occur when the antiarrhythmic drug amiodarone is taken together with either the hepatitis C drug Harvoni (ledipasvir/sofosbuvir) or with Sovaldi (sofosbuvir) taken in combination with another direct acting antiviral for the treatment of hepatitis C infection. FDA is adding information about serious slowing of the heart rate, known as symptomatic bradycardia, to the Harvoni and Sovaldi labels. FDA is recommending that health care professionals should not prescribe either Harvoni or Sovaldi combined with another direct acting antiviral, such as the investigational drug daclatasvir or Olysio (simeprevir), with amiodarone. FDA review of submitted

postmarketing adverse event reports found that patients can develop a serious and life-threatening symptomatic bradycardia when either Harvoni or Sovaldi combined with another direct-acting antiviral is taken together with amiodarone. The reports included the death of one patient due to cardiac arrest and three patients requiring placement of a pacemaker to regulate their heart rhythms. The other patients recovered after discontinuing either the hepatitis C drugs or amiodarone, or both (see Data Summary). The cause of these events could not be determined. FDA will continue to monitor Harvoni and Sovaldi for risks of serious symptomatic bradycardia and further investigate the reason why the use of amiodarone with these hepatitis C drugs led to the heart-related events.

BACKGROUND: For a Data Summary and additional recommendations for health professionals and patients, see the FDA Drug Safety Communication.

RECOMMENDATION: Health care professionals should not prescribe either Harvoni or Sovaldi combined with another direct-acting antiviral drug with amiodarone. However, in cases where alternative treatment options are unavailable, FDA recommends heart monitoring in an inpatient hospital setting for the first 48 hours. Subsequently, monitoring in a doctor's office or self-monitoring of the heart rate should be done every day through at least the first 2 weeks of treatment. Due to the long half-life of amiodarone, patients discontinuing amiodarone just prior to starting Harvoni, or Sovaldi in combination with another direct-acting antiviral, should also undergo similar cardiac monitoring as outlined above. Patients taking either Harvoni or Sovaldi combined with another direct-acting antiviral drug with amiodarone should seek medical attention right away if they experience signs or symptoms of symptomatic bradycardia such as:

- Near-fainting or fainting
- Dizziness or light-headedness
- Malaise
- Weakness
- Excessive tiredness
- Shortness of breath
- Chest pains
- Confusion or memory problems

Source: U.S. Food and Drug Administration (FDA)
Article link:
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm439662.htm

STUDIES and RECENT TOPICS

Use new meningitis vaccines only for outbreaks

February 26, 2015

A federal panel on Thursday recommended that two new meningitis vaccines only be used for rare outbreaks, resisting tearful pleas to give it routinely to teens and college students. The vaccines target B strain meningococcal disease, which comes on like the flu at first but can rapidly develop into dangerous meningitis or blood infections. But it is very rare and students already get another meningitis vaccine that protects against four more common strains.

Article Link:

http://hosted.ap.org/dynamic/stories/U/US_MED_MENINGITIS_VACCINE?SITE=AP&SECTION=HOME&TEMPLATE=DEFAULT&CTIME=2015-02-26-17-24-16

Source: ap.org

Feds warn weight-loss drug contains Prozac

February 28, 2015

The Food and Drug Administration is warning consumers that OxyELITE Pro Super Thermogenic, a supplement marketed for weight loss, contains antidepressant fluoxetine, or Prozac. Consumers should "not purchase or use" the product, officials said in a public notice posted Saturday, noting that it contains the FDA-approved drug Prozac, a selective serotonin reuptake inhibitor (SSRI).

Article Link:

http://thehill.com/blogs/blog-briefing-room/234231-feds-warn-weight-loss-drug-contains-prozac

Source: thehill.com

Feds do Little to Halt Antipsychotic use Among Elderly not in Nursing Homes

March 2, 2015

Responding to concerns that antipsychotics may be too widely prescribed to nursing home residents, a federal government report finds there is widespread overprescribing to the elderly overall. Not only are prescriptions high in nursing homes, but the U.S. Health & Human Services Department has “done little” to address increased prescribing among older adults with dementia living elsewhere.

Article Link:

http://blogs.wsj.com/pharmalot/2015/03/02/feds-do-little-to-halt-antipsychotic-use-among-elderly-not-in-nursing-homes/?mod=WSJBlog

Source: wsj.com

A New Vaccine Targets More HPV Strains

March 2, 2015

A new vaccine has been shown to protect against nine different forms of the cancer-causing human papillomavirus, or HPV, compared with just four strains covered by the current

Gardasil vaccine. But will people use it?
Article Link:
http://well.blogs.nytimes.com/2015/03/02/a-new-vaccine-targets-more-hpv-strains/?_r=1
Source: nytimes.com

Are You Really Allergic to Antibiotics?

March 3, 2015
Allergic reactions to antibiotics can be severe, including symptoms ranging from hives and wheezing to anaphylactic shock. People with such allergic reactions are right to steer clear. The problem is that many, and probably most, people who say they're allergic to antibiotics actually aren't. For penicillin, the most commonly reported allergy, many studies have estimated that up to 90 percent of claims of allergies are not legitimate.
Article Link:
http://www.nytimes.com/2015/03/03/opinion/are-you-really-allergic-to-antibiotics.html?ref=opinion&_r=1
Source: nytimes.com

Common Class of Drugs May Be Linked to Pneumonia Risk

March 3, 2015
Drugs used to treat a wide range of health problems may be associated with an increased risk of pneumonia, a new study suggests.
Anticholinergic medications include those used for conditions such as allergies (for example, Benadryl), overactive bladder (including Ditropan), depression (for example, doxepin) and insomnia (Sominex, etc.).
Article Link:
http://consumer.healthday.com/senior-citizen-information-31/misc-aging-news-10/common-class-of-drugs-may-raise-pneumonia-risk-696949.html
Source Link: healthday.com

FDA warns that testosterone increases heart risks

March 4, 2015
Drug companies who sell testosterone supplements will be required to warn patients that the products may increase the risk for heart attacks and strokes, the Food and Drug Administration announced Tuesday. The agency will require manufacturers of testosterone therapy, available by prescription, to include the warning about potential health risks on product labels.
Article Link:
http://www.usatoday.com/story/news/2015/03/03/fda-testosterone-warning/24326849/
Source: usatoday.com

Spider venom may hold chemical keys to new painkillers

March 4, 2015
Scientists who analyzed countless chemicals in spider venom say they have identified seven

compounds that block a key step in the body's ability to pass pain signals to the brain.
In research they said could one day lead to a new class of potent painkillers, the scientists focused on 206 species of spider and searched for molecules in the venom that block nerve activity, particular via so-called "Nav1.7 channels".
Article Link:
http://www.reuters.com/article/2015/03/04/us-science-pain-venom-idUSKBN0M00B320150304
Source Link: reuters.com

Now, an app that tracks medication shortages

March 4, 2015
Just how bad is the problem of pharmacies not getting enough medication to fill all their customers' prescriptions? Bad enough that the U.S. Food & Drug Administration on Wednesday released a new smartphone app to keep consumers updated on shortages.
Article Link:
http://www.cbsnews.com/news/fda-smartphone-app-tracks-medication-shortages/
Source: cbsnews.com

Orexigen Weight-Loss Pill Shows Surprise Heart-Safety Benefit

March 3, 2015
Obese Americans taking Orexigen Therapeutics'(OREX - Get Report) Contrave to lose weight cut their risk of having a heart attack, stroke or dying from heart disease by almost half compared to people taking a placebo, according to results from a large heart-safety study disclosed for the first time Tuesday.
Article Link:
http://www.thestreet.com/story/13065624/1/orexigen-weight-loss-pill-shows-surprise-heart-safety-benefit.html?puc=yahoo&cm_ven=YAHOO
Source Link: thestreet.com

Common Drug for Irregular Heartbeat Tied to Worse Outcomes

March 4, 2015
Patients who take the heart rhythm drug digoxin may face a nearly 30 percent greater risk of death than patients not taking the drug, a review of prior research suggests.
The analysis also suggests that digoxin may increase the risk for death by 60 to 70 percent among patients with both the heart rhythm disorder known as atrial fibrillation and kidney failure.
Article Link:
http://consumer.healthday.com/cardiovascular-health-information-20/misc-stroke-related-heart-news-360/digoxin-linked-to-higher-death-risk-among-atrial-fibrillation-patients-697088.html
Source Link: healthday.com

Cholesterol-Cutting Statins Found to Raise Diabetes Risk by 46%

March 4, 2015

Millions of people take pills known as statins each year to lower their cholesterol levels. A new study shows the medicine also raises their risk of developing diabetes by 46 percent. The report in the journal Diabetologia found the drugs, including Pfizer Inc.'s Lipitor and AstraZeneca Plc's Crestor, make the body less sensitive to insulin and reduce production of the hormone used to convert blood sugar to energy. Patients should be aware of the potential risk and consider lowering the amount of the medicine they use, said researcher Markku Laakso, a professor at the University of Eastern Finland in Kuopio.

Article Link:

http://www.bloomberg.com/news/articles/2015-03-04/cholesterol-cutting-statins-found-to-raise-diabetes-risk-by-46-

Source Link: Bloomberg.com

Antipsychotic overuse not just a problem in nursing homes

March 4, 2015

Internists, family medicine physicians, psychiatrists and neurologists wrote more than 80% of the prescriptions for antipsychotics for older adults with dementia in 2012, according to a report calling for expanded federal efforts to curb use of the drugs. Though several initiatives have addressed overuse of the medications among nursing home patients who do not have a diagnosis of psychosis, no actions have specifically been directed to other settings, according to a Government Accountability Office report released this week.

Article Link:

http://www.modernhealthcare.com/article/20150304/NEWS/150309951

Source Link: modernhealthcare.com

Clinical trial set to test cannabis oil in Treasure Valley

March 5, 2015

As lawmakers work on amendments to a bill that would legalize cannabis oil, a clinical trial is gearing up to test cannabis oil in the Treasure Valley. The trial will be the first-ever in the Treasure Valley to test the effectiveness of a pharmaceutical-grade cannabis oil or CBD oil known as Epidiolex on children with intractable seizure disorders.

Article Link:

http://www.kboi2.com/news/local/fda_trial-295251641.html

Source Link: kboi2.com

Why death rates among white women are soaring

March 5, 2015

Over the past 15 years, death rates among white women in the United States have mysteriously surged. New research pins blame on an insidious culprit: prescription painkillers. Demographers recently uncovered a startling trend: In 42.8 percent of U.S. counties, mortality rates for women rose between 1992 and 2006. Male rates, meanwhile, increased in a mere 3.4 percent of counties. Between 1999 and 2011, death rates climbed

substantially among only white women, ages 15 to 54. A study from the Urban Institute, published Thursday, attributed half the rise to “accidental poisoning,” or drug overdoses.
Article Link:
http://www.washingtonpost.com/blogs/wonkblog/wp/2015/03/05/the-mysterious-force-behind-rising-death-rates-for-white-women/
Source Link: washingtonpost.com

Painkiller-Addicted Babies a Growing U.S. Concern, Especially in Fla.

March 6, 2015
Newborns suffering from neonatal abstinence syndrome go through a difficult withdrawal Doctors in the United States are seeing more infants born addicted to narcotic painkillers -- a problem highlighted by a new Florida-based report. These infants experience what's called neonatal abstinence syndrome as they undergo withdrawal from the addictive drugs their mothers took during pregnancy. Most often these are narcotic painkillers, such as oxycodone, morphine or hydrocodone, according to the report from the U.S. Centers for Disease Control and Prevention.
Article Link:
http://www.nlm.nih.gov/medlineplus/news/fullstory_151339.html
Source Link: nih.gov

U.S. FDA declines to remove serious warning on Pfizer's Chantix

March 9, 2015
The U.S. Food and Drug Administration has declined to reduce the severity of its warning about neuropsychiatric side effects associated with Pfizer Inc's quit-smoking drug Chantix, the agency said on Monday. The decision follows the recommendation of an advisory committee, which voted last October to keep information about the drug's psychiatric risks, including suicidal thoughts, hostility and agitation, highlighted inside a black box on the package label.
Article Link:
http://www.reuters.com/article/2015/03/09/pfizer-chantix-warning-idUSL1N0WB21820150309
Source Link: reuters.com

Only Long-Term NSAIDs Improve OA Stiffness, Function

March 8, 2015
Long-term use of prescription nonsteroidal anti-inflammatory drugs (NSAIDs) by patients with knee osteoarthritis (OA) is associated with clinically important but not statistically significant improvement in patient-reported stiffness and function and joint-space width, but not pain.
Article Link:
http://www.medpagetoday.com/Rheumatology/Arthritis/50374
Source Link: medpagetoday.com

New Research on Antidepressants and Pregnancy Finds No Link to Asthma

March 9, 2015

Many women with a history of depression who take antidepressants assume that once they get pregnant, they should try to wean themselves off their meds to avoid negative side effects for the baby. A new large study published in the journal Pediatrics challenges one reason behind that assumption. The research found that taking selective serotonin reuptake inhibitors (the antidepressants also known as S.S.R.I.s) while pregnant does not increase the risk of asthma in the resulting babies. What is associated with an increased risk of asthma? According to this study and other research, untreated prenatal depression.

Article Link:

http://parenting.blogs.nytimes.com/2015/03/09/new-research-on-antidepressants-and-pregnancy-finds-no-link-to-asthma/?_r=1

Source Link: nytimes.com

A Time to Avoid Anxiety Drugs

March 9, 2015

People sometimes take Valium or Ativan to relieve anxiety before surgery, but a new study suggests that these benzodiazepine drugs have little beneficial effect and may even delay recovery.

Article Link:

http://well.blogs.nytimes.com/2015/03/09/a-time-to-avoid-anxiety-drugs/?ref=health&_r=0

Source Link: nytimes.com

Quitting smoking? FDA flags alcohol, seizure risks for Chantix users

March 10, 2015

The U.S. Food and Drug Administration is warning smokers who are trying to quit that they may have trouble tolerating alcohol if they are taking Chantix.

Reports made to the FDA and to Chantix manufacturer Pfizer include cases of patients who became more inebriated than usual, were uncharacteristically aggressive and had blacked out after drinking.

Article Link:

http://touch.latimes.com/#section/-1/article/p2p-83022992/

Source Link: latimes.com

Statins May Help Improve Prostate Cancer Survival: Study

March 9, 2015

Cholesterol-lowering statin drugs may slow down prostate cancer in men who are also taking medication to reduce their levels of male hormones, according to new research.

Taking a statin alongside androgen deprivation therapy slowed the progress of prostate cancer by about 10 months, said the study's lead author, Dr. Lauren Christine Harshman, an assistant professor at Dana-Farber Cancer Institute and Harvard Medical School.

Article Link:

http://consumer.healthday.com/cancer-information-5/mis-cancer-news-102/cholesterol-lowering-drugs-may-improve-prostate-cancer-survival-697191.html
Source Link: healthday.com

Mylan Launches First and Only Available Intermediate Dosage Strengths of Fentanyl Transdermal System 37.5, 62.5 and 87.5 mcg/hr

March 11, 2015

Mylan N.V.(MYL) and Mylan Inc. today announced the U.S. launch of its Fentanyl Transdermal System37.5, 62.5 and 87.5 mcg/hr, adding to its existing offering of Fentanyl Transdermal System12, 25, 50, 75 and 100 mcg/hr. Mylan currently is the only manufacturer that offers eight Fentanyl Transdermal System dosage strengths, including three new strengths – the first and only available "intermediate" dosages.

Article Link:
http://finance.yahoo.com/news/mylan-launches-first-only-available-103000065.html
Source Link: Yahoo.com

Antiepileptic Drug May Delay Alzheimer's Dementia in Elderly

March 11, 2015

A common antiepileptic has been found to reverse amnestic mild cognitive impairment (aMCI) in elderly patients with high risk for dementia due to Alzheimer's disease, a study published in NeuroImage: Clinical has found. Scientists from Johns Hopkins University studied an intervention based on animal research demonstrating a beneficial effect on cognition by reducing excess hippocampal neural activity with low doses of the atypical antiepileptic levetiracetam. The double-blind, randomized trial enrolled 84 patients, of which 17 were normal healthy participants and the rest had symptoms of aMCI.

Article Link:
http://www.empr.com/antiepileptic-drug-may-delay-alzheimers-dementia-in-elderly/article/402897/
Source Link: empr.com

RECALLS*

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
	CLASS I				
Drugs	Propofol Injectable Emulsion, 1%, 200 mg/20 mL (10 mg/mL), 20 mL Single patient infusion vials, packaged in 5 Units per carton, Rx only, Hospira, Inc., Lake Forest, IL 60045, NDC 0409-4699-30.	One shipment of Lot #: 33-750-DJ; Exp 1SEP2015 to The Harvard Drug Group, Livonia, MI	Class I	Temperature Abuse: Products experienced uncontrolled temperature excursions during transit.	Hospira Inc.
Drugs	1% LIDOCAINE HCl Injection, USP, Preservative-Free, 10 mg/mL, 30 mL Single-dose vials, packaged in 25-count cartons, Rx only, Hospira, Inc., Lake Forest, IL 60045 USA, NDC 0409-4279-02.	Lot number: 31-427-DK, Exp 01JUL2015.	Class I	Presence of Particulate Matter: Confirmed customer complaint that orange and black particulates, identified as iron oxide, were found embedded within the glass vial and floating in solution.	Hospira Inc.
Drugs	LACTATED RINGER'S and 5% DEXTROSE Injection USP, 1000 mL, flexible containers, Rx Only, Hospira, Inc., Lake Forest, IL 600045, NDC 0409-7929-09	Lot # 35-118- JT, Exp. 11/15	Class I	Non-Sterility: Confirmed customer complaint of particulate matter floating within the solution of the primary container, consistent with mold.	Hospira Inc.
Drugs	1% LIDOCAINE HCl Injection, USP, 10 mg/mL, 30 mL Single-dose, Preservative-Free glass vial (Twenty-five (25) units per box/fifty (50) units per case, NDC 0409-4279-02, Hospira, Inc., Lake Forest, IL 60045	Lot# 40-316-DK, Exp 01APR2016	Class I	Presence of particulate matter: A returned customer sample was evaluated and found to have human hair attached to a pinched area of the stopper.	Hospira Inc.
	CLASS II				
Drugs	Fluconazole Injection,	Lot #: P318394;	Class II	Lack of Assurance of	Baxter

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
	USP, 200 mg/100 mL (2 mg/mL), 100 mL Single-Dose INTRAVIA Container bag, packaged in 10 x 100 mL Single Dose INTRAVIA container bags per carton, Rx only, Baxter Healthcare Corporation, Deerfield, IL 60015 USA, NDC 0338-6046-48, Product Code 2J1446.	Exp 05/31/16		Sterility: Complaints of leaks due to an incomplete seal at the bag seam.	Healthcare Corp.
Drugs	Propofol Injectable Emulsion, 1%, 200 mg/20 mL, (10mg/mL), 20 mL, Single patient infusion vial, Contains Benzyl Alcohol, For I.V. Administration, Hospira, Inc., Lake Forest, IL 60045, NDC 0409-4699-30	Lot 35-844-DJ, Exp 11/01/2015	Class II	Presence of Particulate Matter: The firm received a complaint of an embedded particulate in the neck of one vial composed primarily of iron.	Hospira Inc.
Drugs	Children's Loratadine Syrup (Loratadine Oral Solution) 5 mg/5 mL, Antihistamine, Grape Flavored Syrup, 24 Hour Non-Drowsy Allergy Relief Sugar Free, 4 FL OZ (120 mL) Bottles, Distributed by: Taro Pharmaceuticals U.S.A., Inc. Hawthorne, NY 10532. NDC: 51672-2092-8.	Lot #: A4105, Exp 12/2016	Class II	Presence of Foreign Substance: Presence of blue plastic floating in loratadine syrup.	Taro Pharmaceuticals U.S.A., Inc.
	Levetiracetam, extended release tablets, 750 mg, 60-count bottle, Rx only, Manufactured by Sun Pharmaceutical Ind. Ltd Halol-Baroda Highway, Halol-389 350, Gujarat, India, NDC Number: 47335-576-86	Lot #: JKN0249A Exp 02/2016	Class II	Failed Dissolution Specifications: Failure of dissolution test observed at the 6 month time point	Sun Pharma Global Fze
Drugs	Erythromycin Pledgets USP, 2%, 60-count jar,Rx	Lot # 1446800; Exp. 03/15 Lot #	Class II	Microbial Contamination of	Akorn, Inc.

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
	only, Manufactured by Ei LLC, Kannapolis, NC 28083, Marketed by VersaPharm Incorporated, Marietta, GA 30062, NDC 61748-202-60 .	1538100; Exp. 05/15 Lot # 1538101; Exp. 05/15 Lot # 1538200; Exp. 06/15 Lot # 1608200; Exp. 08/15		Non-Sterile Products: Active Pharmaceutical Ingredient (API) failed USP microbial tests.	
Drugs	Compounded Plaquex, intravenous injection, 50 ML vial. Each ml contains: Phosphatidyl Choline 50 mg, Sodium Deoxycholate 25 mg, Benzyl Alcohol 0.9%, Ethanol (95%) 2.4 mg di Alpha Tocopheryl Acetate 0.2 mg in Sterile Water for injection.	Lot #: 112614-1MC-82186 Exp 5/26/2015; 112614-1MC-82187 Exp 5/26/2015; 112614-1MC-82188 Exp 05/26/205 ;112614-1MC-82189 Exp 5/26/2015	Class II	Good Manufacturing Practices Deviations: The product has an active pharmaceutical ingredient from an unapproved source.	AnazaoHealth Corporation
Drugs	Vancomycin Hydrochloride for Injection, USP, 500 mg Sterile Powder per Fliptop Vial, packaged in 10 Units per carton, Rx only, Hospira, Inc., Lake Forest, IL 60045, NDC 0409-4332-01.	One shipment of Lot #: 34-366-8E02; Exp 1OCT2015 to The Harvard Drug Group, Livonia, MI	Class II	Temperature Abuse: Products experienced uncontrolled temperature excursions during transit.	Hospira Inc.
Drugs	Ketorolac Tromethamine Inj., USP, 60 mg (30 mg/mL), 2 mL Single-dose Fliptop Vial, packaged in 25 Units per carton, Rx only, Hospira, Inc., Lake Forest, IL 60045, NDC 0409-3796-01.	One shipment of Lot #: 34-540-DK; Exp 1OCT2015 to The Harvard Drug Group, Livonia, MI	Class II	Temperature Abuse: Products experienced uncontrolled temperature excursions during transit.	Hospira Inc.
Drugs	Vancomycin Hydrochloride for Injection, USP, 1 g Sterile Powder per Fliptop Vial, packaged in 10 Units per carton, Rx only, Hospira Inc., Lake Forest, IL	Lot #: 35-315-DD; Exp 1NOV2015	Class II	Temperature Abuse: Products experienced uncontrolled temperature excursions during transit.	Hospira Inc.

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
	60045, NDC 0409-6533-01.				
Drugs	Ketorolac Tromethamine Ophthalmic Solution, 0.5%, 3 mL bottle, Rx only, Distributed by: Caraco Pharmaceutical Laboratories Ltd., 1150 Elijah Mccoy Drive, Detroit, MI 48202; Manufactured at: Sun Pharmaceutical Ind. Ltd., Halol-Baroda Highway, Halol-389 350, Gujarat, India; NDC 41616-219-90, UPC 3 41616 21990 6.	Lot #: JKM5035A, Exp 07/15	Class II	Presence of Particulate Matter: lot is not meeting the specification limit for number of particles present in the solution.	Sun Pharma Global Fze
Drugs	Mafenide Acetate, USP, For 5% Topical Solution, STERILE, Net Wt. 50 grams sterile powder per packet, Rx only, PAR Pharmaceuticals label --- Distributed by: Par Pharmaceutical Companies, Inc. Spring Valley, NY 10977 Made in India -- NDC 49884-902-52 (packets of 50 g) and NDC 49884-902-78 (cartons of five 50 g packets)	Lots M13012 (exp. date MAR 2015), M13014 (exp. date MAR 2015), M14036 (exp. date FEB 2016), and M14077 (exp. date JUL 2016)	Class II	Presence of Foreign Substance; oxidized steel, organic material and shredded polypropylene	Par Pharmaceutical Inc.
Drugs	AMLODIPINE BESYLATE TABLETS USP, 10 mg*, 1000 count bottles (NDC 0603-2110-32), Rx only, Manufactured for: QUALITEST PHARMACEUTICALS, HUNTSVILLE, AL 35811	Lot T018H14A, Exp 08/16	Class II	Failed tablet specifications: One lot was found to contain oversized tablets.	Qualitest Pharmaceuticals
Drugs	Dextroamphetamine Sulfate Extended-Release Capsules, 15 mg, 90-count bottles, Rx Only, Manufactured by: Actavis Elizabeth LLC, Elizabeth,	Lot #: 2020E141, Exp 07/15	Class II	Failed Dissolution Specifications	Actavis Elizabeth LLC

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
	NJ 07201 USA; Distributed by: Actavis Pharma, Inc., Parsippany, NJ 07054 USA; NDC 45963-305-09, UPC 3 45963-305-09 1.				
Drugs	Atracurium Besylate Injection, USP, 50 mg per 5 mL (10 mg per mL), Rx Only, 5 mL Single-Dose Vial, For Intravenous Injection, Mfd. for: Sagent Pharmaceuticals, Schaumberg, IL 60195, NDC 25021-659-05	Lot Numbers: VATA012, Exp 11/15; VATA015, Exp 08/16	Class II	Lack of Assurance of Sterility: Recall initiated due to FDA observations pertaining to aseptic and GMP practices at the manufacturers site potentially impacting product sterility.	Sagent Pharmaceuticals Inc
Drugs	Atracurium Besylate Injection, USP, 100 mg per 10 mL (10 mg per mL), Rx Only, 10 mL Multi-Dose Vial, For Intravenous Injection, Mfd. for: Sagent Pharmaceuticals, Schaumberg, IL 60195, NDC 25021-672-10	Lot Numbers: VATB012, VATB013, VATB014, Exp 11/15; VATB017, Exp 08/16	Class II	Lack of Assurance of Sterility: Recall initiated due to FDA observations pertaining to aseptic and GMP practices at the manufacturers site potentially impacting product sterility.	Sagent Pharmaceuticals Inc
Drugs	Fluticasone Propionate Nasal Spray, USP, 50 mcg per spray, in amber glass bottle with net fill weight of 16 g that provides 120 actuations, Rx only, Manufactured by HI-TECH PHARMACAL CO., INC. Amityville, NY 11701 for Akorn Inc. 1925 W. Field Court, Suite 300 Lake Forest Illinois, 60045. NDC 50383-700-16.	Lot #: 631639, Exp 01/2017.	Class II	Failed Stability Specifications: Out of specification for preservative, benazalkonium chloride.	Akorn, Inc.
Drugs	PROMETHAZINE DM SYRUP (Promethazine Hydrochloride, USP and Dextromethorphan Hydrobromide, USP),	Lot #: 0000001099; Exp. 03/16	Class II	Presence of Foriegn Substance: Plastic cap closure particulates may be present in the	Qualitest Pharmaceuticals

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
	EACH 5 ml (ONE TEASPOONFUL) CONTAINS: Promethazine Hydrochloride 6.25 mg, Dextromethorphan Hydrobromide 15 mg, alcohol 7%, ONE PINT (574 mL), Rx only, Manufactured for: QUALITEST PHARMACEUTICALS, HUNTSVILLE, AL 35811, NDC: 0603-1586-58.			product.	
Drugs	DICOPANOL (diphenhydramine hydrochloride in 5 mg/mL oral suspension kit) FusePaq, 150 mL Kits, Rx Only. Fusion Pharmaceuticals LLC., 768 Calle Plano, Camarillo, CA 93012. NDC: 43093-104-01.	Lot Numbers: PL713, PL714, PL715, PL716, PL717, PL718, PL719, PL720, PL721, PL722, PL735, PL736, PL737, PL738, PL739, PL740, PL741, PL742, PL743, PL744; Expiry: 7/20/2015.	Class II	Microbial Contamination of a Non-Sterile Product: Kit component is contaminated with Burkholderia multivorans.	Fusion Pharmaceuticals, LLC
	CLASS III				
Drugs	Z-COTE HP 1 TRANSPARENT ZINC OXIDE, Zinc Oxide (and) Triethoxycaprylylsilane, powder, Net: 22 kg, Packaged in double plastic liners in a single fiber carton, For manufacturing, processing, or repackaging. Nano Technologies Corporation 1319 Marquettte Drive, Romeoville, IL 60446. NDC 10117-3004	Batch #: CNND2902, CNND2903, CNND3001, CNND3002, CNND3003, CNNE0101, CNNE0102, CNNE0103, CNNE0201, CNNE0202, CNNE0203, CNNE0501, CNNE0502, CNNE0503, CNNE0601, CNNE0602,	Class III	Labeling: Illegible label. Writing is rubbing off of labels.	Nanophase Technologies Corporation

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
		CNNE0603, CNNE0701, CNNE0702, CNNE0703, CNNE0801, CNNE0802, CNNE0803, CNNE0901, CNNE0902, CNNE0903, CNNE1201, CNNE1202, CNNE1203, CNNE1204, CNNE1301, CNNE1302, CNNE1303, CNNE1401, CNNE1402, CNNE1403, CNNE1501, CNNE1502, CNNE1503, CNNE1601, CNNE1602, CNNE1603, CNNE1901, CNNE1902, CNNE1903, CNNE2001, CNNE2801, CNNE2802, ... More			
Drugs	Oxecta(TM) (oxycodone HCl) tablets, 5 mg, 100 count bottles, Rx only, Manufactured and Distributed by: King Pharmaceuticals, Inc. Bristol, TN, NDC 60793-525-01	Lot 13T02, Exp. 12/15	Class III	Failed Impurity/Degradation Specification	Pfizer Inc.
Drugs	Oxecta(TM) (oxycodone HCl) tablets, 7.5 mg, 100 count bottles, Rx only, Manufactured and	Lot 13T03, Exp 12/15	Class III	Failed Impurity/Degradation Specification	Pfizer Inc.

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
	Distributed by: King Pharmaceuticals, Inc. Bristol, TN, NDC 60793-526-01				
Drugs	Quinapril Tablets USP, 5 mg, Rx only, 50 tablets (5 X 10) unit dose pack, Manufactured for: AvKARE, Inc., Pulaski, TN 38478, UPC 5026868815, NDC 50268-688-15	Lot number: I1404952, Exp. 02/2016	Class III	Subpotent Drug	AVKARE Inc.
Drugs	Quinapril Tablets USP, 40 mg, Rx only, 50 tablets (5 X 10) unit dose pack, Manufactured for: AvKARE, Inc., Pulaski, TN 38478, UPC 5026869115, NDC 50268-691-15	Lot number: I1407932, Exp. 02/2016	Class III	Subpotent Drug	AVKARE Inc.
Drugs	Simvastatin Tablets, USP, 20mg a) 90- count bottle (42517-0020-10), b) 1000-count-bottle (NDC 42571-0020-10), Rx only, Manufactured by: Micro Labs Limited Goa-403 722, India, Manufactured for: Micro Labs USA Inc.,Princeton, NJ 08540	Lot #: STCG005, Exp 01/2015; Lot #: STCG011, Exp 03/2015; Lot #: STCG012, Exp 02/2015.	Class III	Failed Impurities/Degradation Specifications: Product failed known Impurity specification	Micro Labs Usa, Inc S
Drugs	Simvastatin Tablets, USP, 40mg, Rx Only, 90 count bottles, Manufactured by: Micro Labs Limited Goa-403 722, India, Manufactured for: Micro Labs USA Inc., Princeton, NJ 08540 NDC 42571-0040-90.	Lot #: STDG010, Exp 3/2015	Class III	Failed Impurities/Degradation Specifications: Product failed known Impurity specification	Micro Labs Usa, Inc S
Drugs	Simvastatin Tablets, USP, 80mg, Rx Only, 90 count bottles, Manufactured by: Micro Labs Limited Goa-403 722, India, Manufactured for: Micro Labs USA Inc., Princeton, NJ 08540 NDC 42571-	Lot #: STEG004, Exp 2/2015; Lot #: STEG006 Exp 3/2015	Class III	Failed Impurities/Degradation Specifications: Product failed known Impurity specification	Micro Labs Usa, Inc S

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
	080-90.				
	VACCINES				
Biologics	Immune Globulin Intravenous (Human)	130009; 130011; 130013; 130019; 130021; 130023; 130029; 130033; 130035; 130037; 130039; 130041; 130043; 130137;	Class II	Various lots of BIVIGAM (Immune Globulin Intravenous (Human), 10% Liquid), 100 mL vial, with a potential for a very small percentage of the vials to exhibit a vial integrity defect, were distributed.	Biotest Pharmaceuticals Corp.

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

CURRENT DRUG SHORTAGES‡

Pramipexole Dihydrochloride Tablets

February 25, 2015

Reason for the Shortage

- Avkare, Aurobindo, Mylan, Sandoz, and Torrent cannot provide a reason for the shortage.
- Zydus has pramipexole on allocation due to increased demand.

Article Link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1131
Source link: http://www.ashp.org

Physostigmine Salicylate Injection

February 25, 2015

Reason for the Shortage

- Akorn states the shortage was due to increased demand.

Article Link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1143
Source link: http://www.ashp.org

Polymyxin B Sulfate Injection

February 26, 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

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

February 26, 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

Cyanocobalamin Injection

February 26, 2015

Reason for the Shortage

- American Regent has cyanocobalamin injection on shortage due to manufacturing delays.
- Fresenius Kabi had cyanocobalamin injection on shortage due to increased demand for the product.

Article Link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=947
Source link: http://www.ashp.org

Cefuroxime Sodium Injection

February 26, 2015

Reason for the Shortage

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

Article Link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=990
Source link: http://www.ashp.org

Atropine Sulfate Ophthalmic Solution

February 26, 2015

Reason for the Shortage

- Akorn received FDA approval for atropine sulfate 1% ophthalmic solution in July 2014; this new product launched in January 2015. All other atropine sulfate ophthalmic solution products are unapproved products.
- Sandoz and Valeant could not provide a reason for the shortage.

Article Link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1146
Source link: http://www.ashp.org

Tobramycin Injection

February 27, 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

Metronidazole Injection

February 27, 2015
Reason for the Shortage

- Hospira had 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

Calcium Chloride Injection

February 27, 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

Posaconazole Oral Suspension

March 2, 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

Pantoprazole Injection

March 2, 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

Nicardipine Hydrochloride Injection

March 2, 2015

Reason for the Shortage

- Cornerstone Therapeutics discontinued Cardene ampules in March 2014. The company could not provide a reason for the discontinuation.
- Teva recalled 4 lots nicardipine injection because the product did not meet purity specifications. The recalled lots are 31302508B, 31302510B, 31302957B, 31303195B.
- Teva discontinued nicardipine injection in September, 2010.
- American Regent had temporarily suspended distribution of all drug products in April, 2011.
- American Regent resumed manufacturing in Shirely, New York in early-May, 2011.
- Mylan Institutional could not provide a reason for the shortage.
- Wockhardt has nicardipine on shortage due to an FDA import alert.

Article Link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=31
Source link: http://www.ashp.org

Moxifloxacin Injection

March 2, 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

Cefotaxime Injection

March 2, 2015

Reason for the Shortage

- Fresenius Kabi discontinued all cefotaxime presentations in April 2011.
- Hospira has discontinued Claforan. Sanofi-Aventis manufactured Claforan for Hospira and is no longer making the product.

Article Link:

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

Acyclovir Suspension

March 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

Ceftazidime Injection

March 3, 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

Pantoprazole Tablets

March 4, 2015

Reason for the Shortage

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

Article Link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=979
Source link: http://www.ashp.org

Nafcillin Sodium

March 4, 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

Mannitol Injection

March 4, 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

Amino Acid Products

March 4, 2015
Reason for the Shortage

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

Article Link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=671
Source link: http://www.ashp.org

Sodium Bicarbonate Injection

March 5, 2015
Reason for the Shortage

- Hospira has sodium bicarbonate on back order due to increased demand.
- Amphastar has sodium bicarbonate on back order due to increased demand.

Article Link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=788
Source link: http://www.ashp.org

Cardioplegic Solution for Cardiac Perfusion

March 6, 2015
Reason for the Shortage

- Baxter states the reason for the shortage is increased demand.
- Hospira states the reason for the shortage is manufacturing delay.

Article Link:

http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1172
Source link: http://www.ashp.org

Succinylcholine chloride Injection

March 9, 2015

Reason for the Shortage

- Hospira had Quelicin on shortage due to manufacturing delays. Hospira discontinued Quelicin 100 mg/mL 10 mL vials in early 2014.
- Sandoz had Anectine on shortage due to extra quality reviews.

Article Link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=582
Source link: http://www.ashp.org

Sterile Water Irrigation

March 9, 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

March 9, 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

Reteplase Injection

March 9, 2015

Reason for the Shortage

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

Article Link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=569
Source link: http://www.ashp.org

Propranolol Injection

March 9, 2015

Reason for the Shortage

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

Article Link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1091
Source link: http://www.ashp.org

Proparacaine Hydrochloride Ophthalmic Solution

March 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

Promethazine Injection

March 9, 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

Potassium Phosphate Injection

March 9, 2015

Reason for the Shortage

- American Regent has potassium phosphate injection on back order due to manufacturing delays.
- American Regent has issued a statement that all lots of potassium phosphate may contain glass particles and filters must be used. Do not use if there are visible glass particles and filter all other product.
- Hospira had potassium phosphate 15 mL vials on shortage due to increased demand.

- 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, USA (formerly APP) launched potassium phosphate injection in November 2013.

Article Link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=709
Source link: http://www.ashp.org

Oseltamivir Phosphate

March 9, 2015
Reason for the Shortage

- Genentech had intermittent back orders of Tamiflu due to increased demand for the product.

Article Link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1070
Source link: http://www.ashp.org

Methylphenidate Hydrochloride Immediate Release Tablets

March 9, 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

L-Cysteine Hydrochloride Injection

March 9, 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

Haloperidol Lactate Injection

March 9, 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 could not provide a reason for the shortage.
- 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

Esmolol Injection

March 9, 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

Dipyridamole Injection

March 9, 2015

Reason for the Shortage

- Teva has temporarily discontinued their 2 mL and 10 mL products in order to increase the package sizes.

Article Link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=465
Source Link: http://www.ashp.org

Dimercaprol Injection

March 9, 2015

Reason for the Shortage

- Akorn states BAL in Oil is on shortage due to manufacturing delays.

Article Link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1086
Source Link: http://www.ashp.org

Dexrazoxane Injection

March 9, 2015

Reason for the Shortage

- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired dexrazoxane injection from Bedford in July 2014. West-Ward is not actively marketing dexrazoxane injection at this time.
- Biocodex USA acquired Totect from Apricus Pharmaceuticals in April 2013.
- Apricus Pharmaceuticals acquired Topotarget USA in late 2011.
- Topotarget worked with FDA to extend the expiration date of specific batch numbers of Totect to 36 months. Information regarding this extension and the batch numbers can be found in four Dear Healthcare Customer letters available online.

Article Link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=415
Source Link: http://www.ashp.org

Aminohippurate Sodium

March 9, 2015

Reason for the Shortage

- Merck cannot provide a reason for the shortage.

Article Link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1135
Source Link: http://www.ashp.org

Tamoxifen Tablets

March 10, 2015

Reason for the Shortage

- Teva could not provide a reason for the shortage.
- Mylan discontinued tamoxifen 10 mg 500 count and 20 mg 100 count presentations.
- Actavis could not provide a reason for the shortage.

Article Link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1071
Source Link: http://www.ashp.org

Ceftriaxone Sodium Injection

March 10, 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

Cefazolin Injection

March 10, 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

Azithromycin Injection

March 10, 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 had 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

Ondansetron Injection

March 11, 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.
- Heritage cannot provide a reason for the shortage.
- Hospira had ondansetron on shortage due to manufacturing delays
- Mylan Institutional has new NDC numbers for ondansetron 2 mg/mL injectable products.
- Teva re-launched ondansetron 20 mL injection in 2015.
- West-Ward had ondansetron on back order due to increased demand.
- Wockhardt has ondansetron injection on 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

Ciprofloxacin Injection

March 11, 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

Barium Sulfate Oral Suspension

March 11, 2015

Reason for the Shortage

- Bracco Diagnostics states the reason for the shortage is manufacturing delay, as well as increased demand. Bracco Diagnostics has provided a customer letter detailing the reason for the shortage and barium sulfate presentations affected.
- Bracco discontinued multiple products in August 2013 in order to streamline their product portfolio. Table 1 summarizes the barium products that were discontinued. Bracco has provided an updated product portfolio detailing the product changes and the recommended alternate products.

Article Link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=963
Source Link: http://www.ashp.org

Midazolam Injections

March 12, 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.

Article Link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=858
Source Link: http://www.ashp.org

Sterile Water for Injection Large Volume Bags

March 13, 2015

Reason for the Shortage

- Baxter has sterile water for injection on shortage due manufacturing delays.
- BBraun has sterile water for injection on shortage due to increased demand and only has product available for existing customers.
- Hospira has sterile water for injection on shortage due to increased demand and only has product available for existing customers.

Article Link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1132
Source Link: http://www.ashp.org

Sodium Chloride 0.45% Injection Bags

March 13, 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

Mesna Injection

March 13, 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

Calcium Gluconate Injection

March 13, 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

March 13, 2015

Reason for the Shortage

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

Amikacin Injection

March 13, 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 cannot provide a reason for the shortage.

Article Link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=501
Source Link: http://www.ashp.org

Oxytocin Injection

March 16, 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 cannot provide a reason for the shortage.

Article Link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=876
Source Link: http://www.ashp.org

Oxycodone/Acetaminophen Oral Solution

March 16, 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

Metoprolol Injection

March 16, 2015
Reason for the Shortage

- American Regent and Sagent have 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

Ezetimibe and Atorvastatin Tablets

March 16, 2015
Reason for the Shortage

- In January 2014, Merck recalled all Liptruzet lots from wholesalers due to packaging defects in the outer laminate foil pouches.

Article Link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1084
Source Link: http://www.ashp.org

Amoxicillin 875 mg Tablets

March 16, 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

Levocarnitine Injection

March 18, 2015

Reason for the Shortage

- American Regent has levocarnitine injection on back order due to manufacturing delays.
- Teva has discontinued levocarnitine injection in late 2014.
- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired several products from Bedford Laboratories in July 2014 including levocarnitine injection. West-Ward is not actively marketing levocarnitine injection.

Article Link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=968
Source Link: http://www.ashp.org

Indigo Carmine Injection

March 18, 2015

Reason for the Shortage

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

Article Link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=861
Source Link: http://www.ashp.org

Digoxin Injection

March 18, 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

Butorphanol Injection

March 18, 2015

Reason for the Shortage

- Apotex discontinued butorphanol injection in 2008.
- Ben Venue closed its plant in Bedford, Ohio in July 2014.
- Hospira states the shortage was due to manufacturing delays.
- West-Ward discontinued butorphanol injection in early 2012.
- Sandoz discontinued Stadol injection in 2010.

Article Link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=939
Source Link: http://www.ashp.org

Azathioprine Tablets

March 18, 2015

Reason for the Shortage

- Roxane discontinued azathioprine tablets in mid-January 2015 due to problems obtaining active ingredient.
- 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

Anagrelide Capsules

March 18, 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

Vasopressin Injection

March 19, 2015

Reason for the Shortage

- American Regent discontinued vasopressin injection in early 2015.
- Par Sterile Products (formerly JHP) discontinued Pitressin injection in November 2014.
- Par Sterile Products introduced Vasostrict injection in November 2014. This is the only FDA-approved vasopressin injection.
- Fresenius Kabi will discontinue distributing vasopressin on March 15, 2015. A letter is available regarding this discontinuation.

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

Source Link: http://www.ashp.org

Sufentanil Injection

March 19, 2015

Reason for the Shortage

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

Article Link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=823
Source Link: http://www.ashp.org

Epinephrine Injection

March 19, 2015

Reason for the Shortage

- American Regent discontinued both epinephrine presentations in early-2015.
- Amphastar states the shortage is due to increased demand.
- BPI Labs received FDA approval for epinephrine 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

Ammonium Chloride Injection

March 19, 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

Prochlorperazine Edisylate Injection

March 20, 2015

Reason for the Shortage

- Heritage Pharmaceuticals could not provide a reason for the shortage.

Article Link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1063
Source Link: http://www.ashp.org

Methylprednisolone Acetate Injection

March 20, 2015

Reason for the Shortage

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

Article Link:

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

Source Link: http://www.ashp.org

Ketorolac Tromethamine Injection

March 20, 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

Ethambutol Tablets

March 20, 2015

Reason for the Shortage

- Akorn acquired VersaPharm, Inc. in 2014.
- Akorn could not provide a reason for the shortage.
- X-Gen could not provide a reason for the shortage.
- G&W Laboratories discontinued ethambutol tablets in mid-April 2013.

Article Link:

http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=982

Source Link: http://www.ashp.org

Caffeine Citrate Injection and Oral Solution

March 20, 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

Ampicillin Sulbactam

March 20, 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

Acetaminophen and Codeine Phosphate 300 mg/30 mg Tablets

March 20, 2015
Reason for the Shortage

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

Article Link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1152
Source Link: http://www.ashp.org

Vecuronium Bromide Injection

March 23, 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

Vancomycin Hydrochloride Injection

March 23, 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

Torsemide Injection

March 23, 2015

Reason for the Shortage

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

Article Link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=344
Source Link: http://www.ashp.org

Tolterodine Tartrate Extended Release Capsules

March 23, 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

Testosterone Cypionate Intramuscular Injection

March 23, 2015

Reason for the Shortage

- Actavis discontinued testosterone cypionate injection in 2015.
- Paddock has testosterone on shortage due to increased demand and shipping delays from their contract manufacturer.
- West-Ward had testosterone cypionate on shortage due to manufacturing delays.
- Sandoz discontinued testosterone cypionate 200 mg/mL 1 mL and 10 mL vials in September 2011. Sandoz discontinued final presentation in first half of 2012.

Article Link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=638
Source Link: http://www.ashp.org

Tamsulosin Hydrochloride Capsules

March 23, 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

Tacrolimus Capsules

March 23, 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

Sumatriptan Succinate Injection

March 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

Prednisone Tablets

March 23, 2015

Reason for the Shortage

- Cadista states the shortage was due to a raw materials shortage.
- Perrigo discontinued prednisone tablets in 2013.
- Qualitest will not provide shortage information for any of their products because they consider the information to be proprietary.
- 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

Potassium Chloride Injection

March 23, 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

Phenylephrine 2.5% and 10% Ophthalmic Solution

March 23, 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 mid-March 2015.
- Alcon discontinued phenylephrine 2.5% ophthalmic solution with the Sandoz label in April 2014.

- Alcon discontinued Mydfrin 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

Pancuronium Injection

March 23, 2015
Reason for the Shortage

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

Article Link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=851
Source Link: http://www.ashp.org

Nebivolol Tablets

March 23, 2015
Reason for the Shortage

- Actavis could not provide a reason for the shortage.

Article Link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1137
Source Link: http://www.ashp.org

Nalbuphine Injection

March 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

Morrhuate Sodium Injection

March 23, 2015
Reason for the Shortage

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

Article Link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=903
Source Link: http://www.ashp.org

Methylphenidate Hydrochloride Extended Release Oral Presentations

March 23, 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

Lidocaine Hydrochloride Oral Topical Solution (Viscous) 2%

March 23, 2015

Reason for the Shortage

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

Article Link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1171
Source Link: http://www.ashp.org

Lidocaine Injection

March 23, 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

Leuprolide Acetate 14-Day Kit

March 23, 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

Leucovorin Calcium Injection

March 23, 2015
Reason for the Shortage

- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired leucovorin calcium injection from Bedford in July 2014. West-Ward is not actively marketing leucovorin calcium injection at this time.
- Teva had leucovorin on shortage due to manufacturing delays. Teva imported leucovorin calcium (calcium folinate solution) 30 mL vials; however, all product expired in July 2014. Teva will not be importing any additional calcium folinate solution.
- Fresenius Kabi (formerly APP) has leucovorin on shortage due to increase demand.
- Fusilev (levoleucovorin) and leucovorin oral tablets are not affected by the shortage.

Article Link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=488
Source link: http://www.ashp.org

Lactated Ringer's Injection Bags

March 23, 2015
Reason for the Shortage

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

Article Link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1078
Source link: http://www.ashp.org

Hydroxyzine Injection

March 23, 2015

Reason for the Shortage

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

Article Link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=829
Source link: http://www.ashp.org

Hydroxychloroquine Sulfate Tablets

March 23, 2015

Reason for the Shortage

- Ranbaxy has hydroxychloroquine on shortage due to a regulatory issue.
- Sandoz states the hydroxychloroquine shortage is due to increased demand.
- Zydus could not provide a reason for hydroxychloroquine shortage.
- West-Ward discontinued hydroxychloroquine tablets in September 2014.

Article Link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1126
Source link: http://www.ashp.org

Hydralazine Injection

March 23, 2015

Reason for the Shortage

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

Article Link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1129
Source link: http://www.ashp.org

Haloperidol Decanoate Injection

March 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

Fluconazole Injection

March 23, 2015

Reason for the Shortage

- Teva is not relaunching fluconazole injection.
- Pfizer had fluconazole injection on shortage due to manufacturing delays related to labeling changes.
- West-Ward had fluconazole injection on shortage due to manufacturing delays.
- Ben Venue has 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=644
Source link: http://www.ashp.org

Fenoldopam Mesylate Injection

March 23, 2015

Reason for the Shortage

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

Article Link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1031
Source link: http://www.ashp.org

Famotidine Injection

March 23, 2015

Reason for the Shortage

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

Article Link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=810
Source link: http://www.ashp.org

Etomidate Injection

March 23, 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

Droperidol Injection

March 23, 2015
Reason for the Shortage

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

Article Link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=818
Source link: http://www.ashp.org

Dexpanthenol Injection

March 23, 2015
Reason for the Shortage

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

Article Link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1103
Source link: http://www.ashp.org

Desmopressin Injection

March 23, 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

Deferoxamine Mesylate Injection

March 23, 2015
Reason for the Shortage

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

- 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

Cisatracurium Injection

March 23, 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

Chorionic Gonadotropin (Human) Injection

March 23, 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?sort=2
Source link: http://www.ashp.org

Cefpodoxime

March 23, 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?sort=2
Source link: http://www.ashp.org

Bupivacaine Injection

March 23, 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

Benzonatate Capsules

March 23, 2015

Reason for the Shortage

- Amneal and Ascend Laboratories cannot provide a reason for the shortage.
- Caraco will discontinue benzonatate capsules when current supplies are depleted.
- Zydus states the reason for the shortage is manufacturing delay.

Article Link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1155
Source link: http://www.ashp.org

Azathioprine Injection

March 23, 2015

Reason for the Shortage

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

Article Link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=935
Source link: http://www.ashp.org

Alcohol Dehydrated Injection (Ethanol)

March 23, 2015

Reason for the Shortage

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

Article Link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=778
Source link: http://www.ashp.org

Acetylcysteine Inhalation Solution

March 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

70% Dextrose Injection Large Volume Bags

Mar 23, 2015

Reason for the Shortage

- Baxter discontinued 70% dextrose 500 mL in 1000 mL partial-fill bags in late-2014.
- Baxter, BBraun, and Hospira state the reason for the shortage is increased demand for product.

Article Link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1133
Source link: http://www.ashp.org

Zinc Injection

March 24, 2015

Reason for the Shortage

- Hospira states the shortage of zinc chloride injection was 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 Aguettant 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

Sterile Empty Vials

March 24, 2015

Reason for the Shortage

- Hospira states the shortage is due to increased demand.
- Fresenius Kabi (formerly APP) reduced production of sterile empty vials to permit increased production of drug products affected by critical shortages.
- Sterile empty vials may be available from medical supply distributors

Article Link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=890
Source link: http://www.ashp.org

Disopyramide Phosphate Controlled-release Capsules

March 24, 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

Atorvastatin Tablets

March 24, 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 has atorvastatin tablets on allocation due to increased demand.
- Greenstone states the shortage is due to manufacturing delays.
- 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

Vitamin E Aqueous Oral Solution

March 25, 2015

Reason for the Shortage

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

Article Link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=965
Source link: http://www.ashp.org

Trace Elements Injection

March 25, 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

Sodium Chloride Concentrated Solution for Injection

March 25, 2015

Reason for the Shortage

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

Article Link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=724
Source link: http://www.ashp.org

Piperacillin Tazobactam Injection

March 25, 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 September 2015 for the single dose vials and 1st quarter 2017 for the bulk vials.
- WG Critical Care states the reason for the shortage is increased demand.

Article Link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1075
Source link: http://www.ashp.org

Papaverine Injection

March 25, 2015

Reason for the Shortage

- Bedford and Sandoz have discontinued their papaverine presentations.
- American Regent has papaverine on shortage due to manufacturing delays.
- American Regent is the sole supplier of papaverine.

Article Link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=781
Source link: http://www.ashp.org

Mercaptopurine Tablets

March 25, 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

Magnesium Sulfate Injection

March 25, 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

Indocyanine Green

March 25, 2015

Reason for the Shortage

- Akorn states the reason for the shortage was increased demand.
- Hub Pharmaceuticals states the reason for the shortage is increased demand.

Article Link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1107
Source link: http://www.ashp.org

Doxycycline Capsules and Tablets

March 25, 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

Divalproex Sodium Delayed Release Tablets

March 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

Dexamethasone Sodium Phosphate

March 25, 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 Insitutional 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

Bupropion Hydrochloride 24 hour ER Tablets

March 25, 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

Benztropine Injection

March 25, 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

Atenolol Tablets

March 25, 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

Methotrexate Injection

March 26, 2015

Reason for the Shortage

- Mylan Institutional cannot provide a reason for the shortage.
- Sandoz states the reason for the shortage is manufacturing delay.
- 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 Liposomal Injection

March 26, 2015

Reason for the Shortage

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

Article Link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=806
Source link: http://www.ashp.org

Doxorubicin Injection

March 26, 2015

Reason for the Shortage

- West-Ward Pharmacetuicals' parent company, Hikma Pharmaceuticals, acquired Adriamycin injection from Bedford in July 2014. West-Ward is not actively marketing Adriamycin injection at this time.
- Pfizer had doxorubicin solution for injection on shortage due to shipping delays.
- Sagent introduced doxorubicin injection in November 2013.
- Sagent has doxorubicin on shortage due to manufacturing delays.
- Mylan Institutional acquired doxorubicin lyophilized powder from Pfizer on December 6, 2013.
- Teva could not provide a reason for the shortage.

Article Link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=464
Source link: http://www.ashp.org

Daunorubicin Hydrochloride Injection

March 26, 2015

Reason for the Shortage

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

Article Link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1007
Source link: http://www.ashp.org

Cisplatin Injection

March 26, 2015

Reason for the Shortage

- Fresenius states the shortage was due to increased demand and manufacturing delays.
- Mylan Institutional cannot provide a reason for the shortage.
- Teva was allocating cisplatin to prevent stockpiling.
- WG Critical Care was allocating product due to increased demand.

Article Link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=57
Source link: http://www.ashp.org

Carboplatin Solution for Injection

March 26, 2015

Reason for the Shortage

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

Article Link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1005
Source link: http://www.ashp.org

Lidocaine with Epinephrine Injection

March 27, 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

Heparin Premixed Bags

Mar 27, 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

Atracurium Injection

March 27, 2015

Reason for the Shortage

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

Article Link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=872
Source link: http://www.ashp.org

Adenosine Injection

March 27, 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 increased demand.
- 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

Acetazolamide Injection

Mar 27, 2015

Reason for the Shortage

- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired acetazolamide injection from Bedford in July 2014. West-Ward is not actively marketing acetazolamide injection at this time.
- Sagent has acetazolamide injection on shortage due to manufacturing delay.

Article Link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=463
Source link: http://www.ashp.org

Fomepizole Injection

March 30, 2015

Reason for the Shortage

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

Article Link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1173
Source link: http://www.ashp.org

Dextrose 5% Injection Large Volume Bags

March 30, 2015

Reason for the Shortage

- Baxter states the shortage is due to increased demand.
- BBraun had 5% dextrose on allocation due to increased demand.
- 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

Dacarbazine Injection

March 30, 2015

Reason for the Shortage

- Fresenius states the reason for the shortage was increased demand.
- Teva and Hospira had dacarbazine on back order due to manufacturing delays.
- 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.

Article Link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=949
Source link: http://www.ashp.org

Cytarabine Injection

March 30, 2015

Reason for the Shortage

- Fresenius Kabi has cytarabine on shortage due to increased demand.
- Mylan Institutional cannot provide a reason for the shortage.
- West-Ward is not currently marketing cytarabine.

Article Link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=413
Source link: http://www.ashp.org

Clindamycin Injection

March 30, 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

Chlorothiazide Oral Suspension

March 30, 2015

Reason for the Shortage

- Salix cannot provide a reason for the shortage.
- Salix is the sole supplier of chlorothiazide oral suspension.

Article Link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1076
Source link: http://www.ashp.org

BCG Vaccine Live Intravesical

March 30, 2015

Reason for the Shortage

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

Article Link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=915
Source link: http://www.ashp.org

Acamprosate Calcium Tablets

March 30, 2015

Reason for the Shortage

- Glenmark Pharmaceuticals cannot provide a reason for the shortage.
- Mylan cannot provide a reason for the shortage.
- Actavis discontinued Campral tablets in 2014.

Article Link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1170
Source link: http://www.ashp.org

Multiple Vitamins for Infusion

March 31, 2015

Reason for the Shortage

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

Article Link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=831
Source link: http://www.ashp.org

Morphine Injections

March 31, 2015

Reason for the Shortage

- Fresenius Kabi states the shortage is due to a change in manufacturing sites and cannot estimate when Astramorph will return.
- Hospira states the shortage is due to manufacturing delays.
- West-Ward states the shortage was due to increased demand for product.

Article Link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=664
Source link: http://www.ashp.org

Methylene Blue Injection

March 31, 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

March 31, 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

Lactated Ringer's Irrigation

March 31, 2015

Reason for the Shortage

- Baxter has lactated ringer's on shortage due manufacturing delays.
- BBraun has lactated ringer's irrigation on shortage due to increased demand.
- Hospira has lactated ringer's irrigation available.

Article Link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1119
Source link: http://www.ashp.org

Fluorescein sodium injection

March 31, 2015

Reason for the Shortage

- Altaire Pharmaceuticals temporarily discontinued fluorescein and fluorescein lite products. Altaire Pharmaceuticals could not provide a reason for the temporary discontinuation.

Article Link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1104
Source link: http://www.ashp.org

Diltiazem Injection

March 31, 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

* Please refer to ASHP website for more information

NEW DRUGS COMING TO MARKET

PRODUCT	MFR	ROUTE	INDICATION	PHARMACOLOGY	MARKET RELEASE
LY2963016	Boehringer Ingelheim/ Eli Lilly	INJ (SC)	Type I and II diabetes	Novel version of insulin glargine (biosimilar to Lantus)	NDA was filed 12-2013 under 505(b)(2) application; received tentative approval 8/2014; patent infringement lawsuit may delay launch beyond 2/2015
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
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 controlled by the If current	NDA filed 6/2014; FDA fast-track and priority review with action day of 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

PRODUCT	MFR	ROUTE	INDICATION	PHARMACOLOGY	MARKET RELEASE
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
Eluxadoline (JNJ-27018966)	Janssen/ Furiex	PO	Irritable bowel syndrome	Opioid delta receptor antagonists; opioid 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
Drisapersen	Prosensa	INJ (SC)	Duchenne Muscular Dystrophy	Antisense nucleotide that induced specific skipping of exon 51 during splicing	Phase III; FDA breakthrough therapy designation granted 6/2013; Rolling NDA initiated 10/2014
Olodaterol/tio-tropium	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/lu-macaftor	Vertex	PO	Cystic fibrosis	Fixed-dose combination of lumacaftor and	FDA Breakthrough Therapy

PRODUCT	MFR	ROUTE	INDICATION	PHARMACOLOGY	MARKET RELEASE
				ivacaftor (transmembrane conductance regulator stimulants)	Designation 1/2013; NDA filed 11/2014
Asfotase	Enobia Pharma	INJ (SC)	Hypophosphatasia	Recombinant fusion protein that includes the catalytic domain of human tissue non-specific alkaline phosphate (TNSALP)	FDA breakthrough therapy designation 5/2013; rolling BLA initiated 4/2014
Patiromer	Relypsa	PO	Hyperkalemia	Non-absorbed oral polymeric compound known as patiromer, a potassium binder	NDA filed 10/2014
CEP-33237	Teva	PO	Moderate to severe pain	Hydrocodone extended release with abuse deterrent properties; dosed once daily	Phase III; Rolling NDA initiated 10/2014
MNK-155	Mallinkrodt	PO	Moderate to moderately severe acute pain	Hydrocodone and acetaminophen extended release	NDA submitted 5/2014