



February-March 2016
Drug Information Update

Table of Contents

NEW GENERICS TO MARKET	2
NEW DRUG ENTITIES.....	3
NEW INDICATIONS (EXISTING DRUGS)	5
FDA NEWS/BULLETINS/ADVISORIES/SAFETY ALERTS	6
STUDIES and RECENT TOPICS.....	10
RECALLS.....	18
CURRENT DRUG SHORTAGES.....	35
NEW DRUGS COMING TO MARKET.....	57

NEW GENERICS TO MARKET

GENERIC DRUG NAME	STRENGTH & DOSAGE FORM	GENERIC MANUFACTURER	BRAND NAME	APPROVAL DATE
Cyclopentolate Hcl	0.5% Drops	Akorn Inc	CYCLOGYL	02/17/2016
Benzphetamine Hcl	25mg tablet	Nivagen	REGIMEX	02/23/2016
Ephedrine Sulfate-0.9% NaCl	25 mg/5 mL (5 mg/mL) Syringe	Pharmedium	EPHEDRINE SULFATE/0.9% NACL/PF	03/03/2016
Magnesium Sulfate-0.9% NaCl	6 gram/150 mL (40 mg/mL) Piggyback	Pharmedium	MAGNESIUM SULFATE IN 0.9% NACL	03/03/2016
Vancomycin/0.9 % Sod Chloride	750mg/250mL Plastic Bag	Pharmedium	VANCOMYCIN HCL- 0.9% NACL	03/04/2016
Neostigmine Methylsulfate	2 mg/2 mL (1 mg/mL) Syringe	Pharmedium	NEOSTIGMINE METHYLSULFATE	03/04/2016
Oxiconazole Nitrate	1% Cream	Taro Pharm	OXISTAT	03/08/2016
Doxepin Hcl	5% Cream	Renaissance	PRUDOXIN	03/09/2016

NEW DRUG ENTITIES

DESCRIPTION	BRAND NAME	GENERIC NAME	STRENGTH	NOTES
Cardioplegic Solutions	Cardioplegia Del Nido Formula	Cardioplegic Solution No.16	26/1052.8	New Combination
Analgesic, Non-Salicylate & Barbiturate Comb.	Allzital	Butalbital/Acetaminophen	25MG-325MG	New Strength
Antipsychotic-Atypical,D3/D2 Partial Ag-5ht Mixed	Vraylar	Cariprazine Hydrochloride	1.5, 3, 4.5, and 6mg	New Entity
Antipsychotic-Atypical,D3/D2 Partial Ag-5ht Mixed	Vraylar	Cariprazine Hydrochloride	1.5 MG-3MG	New Entity
Ear Preparations,Antibiotics	Otiprio	Ciprofloxacin	6 %	New Strength
Pediatric Vitamin Preparations	Floriva Plus	Pedi Multivit No.130/Fluoride	0.25 mg fluoride (0.55 mg)/mL	New combination
Chemotherapy Rescue/Antidote Agents	Vistogard	Uridine Triacetate	10 gram	New Strength
Insulins	Humulin R U-500 Kwikpen	Insulin Regular, Human	500 unit/mL (3 mL) (concentrated)	New strength
Anticonvulsants	Spritam	Levetiracetam	250, 500, 750, and 1000 mg	New dosage form
Beta-Adrenergic Blocking Agents	Metoprolol Tartrate	Metoprolol Tartrate	37.5 and 75 mg	New strength
Anti-Inflammatory/Antiarthritics Agents, Misc.	Hymovis	Hyaluronate,Mod.,Non-Crosslink	24 mg/3 mL	New entity
Artv Cmb Nucleoside,Nucleotide,&Non-Nucleoside Rti	Odefsey	Emtricitab/Rilpiviri/Tenof Ala	200 mg-25 mg-25 mg	New entity
Janus Kinase (Jak) Inhibitors	Xeljanz XR	Tofacitinib Citrate	11 mg	New dosage form
Non-Narc Antitus-1st Gen Antihist-Decongest-Expect	Donatussin	Chlorpheniramine-Phenyleph-DM-Gg	n/a	New Combination
Non-Narc Antitus-1st Gen Antihist-Decongest-Expect	Tonecol Cough	Chlorpheniramine-Phenyleph-DM-Gg	n/a	New Combination
Non-Narc Antitus-1st Gen Antihist-Decongest-Expect	Tussilan	Chlorpheniramine-Phenyleph-Dm-Gg	n/a	New Combination
Non-Narc Antitus-1st Gen Antihist-Decongest-Expect	Chem-Tuss Dme	Chlorpheniramine-Phenyleph-Dm-Gg	n/a	New Combination
Non-Narc Antitus-1st Gen Antihist-Decongest-Expect	No Cough Plus	Chlorpheniramine-Phenyleph-Dm-Gg	n/a	New Combination
Non-Narc Antitus-1st Gen Antihist-Decongest-Expect	Donatussin	Chlorpheniramine-Phenyleph-Dm-Gg	n/a	New Combination

DESCRIPTION	BRAND NAME	GENERIC NAME	STRENGTH	NOTES
Non-Narc Antitus-1st Gen Antihist-Decongest-Expect	Donatussin	Chlorpheniramn-Phenyleph-Dm-Gg	n/a	New Combination
Non-Narc Antitus-1st Gen Antihist-Decongest-Expect	Tussigen-N.F.	Chlorpheniramn-Phenyleph-Dm-Gg	n/a	New Combination
Factor IX Preparations	Idelvion	Factor Ix Recom,Albumin Fusion	250 (+/-) unit range	New Entity
Factor IX Preparations	Idelvion	Factor Ix Recom,Albumin Fusion	500 (+/-) unit range	New Entity
Factor IX Preparations	Idelvion	Factor Ix Recom,Albumin Fusion	1,000 (+/-) unit range	New Entity
Factor IX Preparations	Idelvion	Factor Ix Recom,Albumin Fusion	2,000 (+/-) unit range	New Entity

NEW INDICATIONS (EXISTING DRUGS)

DRUG	NEW INDICATION	DATE OF APPROVAL	LINKS
Harvoni (ledipasvir/sofosbuvir)	HCV with advance liver disease	02/16/2016	Harvoni [package insert] Gilead. February 2016
Xeljanz XR (tofacitinib)	Moderate to severe rheumatoid arthritis	02/24/2016	Xeljanz XR [package insert] Pfizer Inc. February 2016
Gazyva (obinutuzumab)	Combination Treatment Of Previously Treated Follicular Lymphoma	02/26/2016	Gazyva [package insert] Genentech. February 2016.
Afinitor (everolimus)	Progressive, Nonfunctional, Gastrointestinal And Lung Neuroendocrine Tumors (NET)	02/26/2016	Afinitor [package insert] Novartis. February 2016.
Faslodex (fulvestrant)	Combination therapy for metastatic, treatment epiirienced, HR+, HER- breast cancer	03/02/2016	Faslodex [package insert] AstraZeneca. March 2016.
Imbruvica (ibrutinib)	First-Line For The Treatment Of Chronic Lymphocytic Leukemia (CLL)	03/04/2016	Imbruvica [package insert] Pharmacyclics Inc. March 2016
Xalkori (crizotinib)	Treatment Of ROS-1 Positive Non-Small Cell Lung Cancer	03/11/2016	Xalkori [package insert] Pfizer Inc. March 2016.

FDA NEWS/BULLETINS/ADVISORIES/SAFETY ALERTS

FDA announces Pharmakon Pharmaceuticals voluntary recall of morphine sulfate 0.5 mg/mL preservative free in 0.9% sodium chloride

[Posted: 2/16/2016] The U.S. Food and Drug Administration is alerting health care professionals of a voluntary recall of morphine sulfate 0.5 mg/mL preservative free in 0.9% sodium chloride, 1 mL syringe, CII, for intravenous use made and distributed by Pharmakon Pharmaceuticals, in Noblesville, Indiana, because the product is super-potent. Pharmakon initiated the voluntary recall on February 11, 2016, after receiving laboratory results showing the product was super-potent.

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

Fluconazole Injection, USP, (in 0.9 Percent Sodium Chloride) 200mg per 100ml: Recall - Elevated Impurity

[Posted: 3/1/2016]

ISSUE: Sagent has initiated a voluntary recall of one lot of Fluconazole Injection, USP, 200mg per 100mL to the user level due to the discovery of an out of specification impurity result detected during routine quality testing of stability samples at the 18-month interval. This impurity has been identified as Metronidazole. An elevated impurity has the potential to decrease effectiveness of the product in patients. Patients on the product and on concomitant medication of Metronidazole may receive an increased dose of Metronidazole.

BACKGROUND: The lot number being recalled is Lot 40608 which was distributed to hospitals, wholesalers and distributors nationwide from November 2014 through December 2014. Fluconazole Injection, USP, 200mg per 100mL is indicated, for the treatment of Oropharyngeal and esophageal candidiasis, cryptococcal meningitis, and is supplied in 100mL and 200mL flexible container bags.

RECOMMENDATION: Customers have been instructed to examine their inventory immediately and to quarantine, discontinue distribution of and return the recalled lot 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

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

FDA alerts health care professionals and patients not to use human and animal sterile drug products produced and distributed by I.V. Specialty, Ltd., Austin, Texas

[Posted: 03/09/2016] The U.S. Food and Drug Administration is alerting health care professionals and patients not to use drug products intended to be sterile that are produced and distributed by I.V. Specialty Ltd., Austin, Texas, due to lack of sterility assurance.

Health care professionals and consumers should immediately check their medical supplies, quarantine any drug products labeled as sterile from I.V. Specialty, and not administer them to patients. Health care professionals should make alternative arrangements to obtain any medications they administer to patients from reliable sources that adhere to proper quality standards.

During FDA's recent inspection of I.V. Specialty, investigators observed insanitary conditions, including poor sterile production practices, which raise concerns about I.V. Specialty's ability to assure the sterility of the drug products it produces. Administration of a non-sterile product intended to be sterile may result in serious and potentially life threatening infections or death.

On March 7, 2016, FDA recommended that I.V. Specialty cease sterile production until appropriate corrective actions are implemented, and recall all non-expired drug products intended to be sterile. The company has neither ceased sterile production nor initiated a recall. Therefore, FDA is alerting health care professionals and patients to dispose of and not use drug products intended to be sterile that were produced and distributed by I.V. Specialty.

To date, FDA is not aware of any reports of adverse events associated with drug products produced by I.V. Specialty. Patients who have received drug products produced by I.V. Specialty and have concerns should contact their health care professional.

FDA encourages health care professionals and patients to report adverse reactions or quality problems experienced with the use of human drug products from I.V. Specialty to FDA's MedWatch Adverse Event Reporting program:

- Complete and submit the report online at www.fda.gov/medwatch/report.htm; or
- Download and complete the form, then submit it via fax at 1-800-FDA-0178

For reporting animal adverse drug events, please follow the link to the FORM FDA 1932a found at: <http://www.fda.gov/AnimalVeterinary/SafetyHealth/ReportaProblem/ucm055305.htm>

Link: <http://www.fda.gov/Drugs/DrugSafety/ucm489951.htm>

FDA Alerts Healthcare Professionals About Clinical Trials with Zydelig (idelalisib) in Combination with other Cancer Medicines

[Posted 3/14/2016] The U.S. Food and Drug Administration is alerting health care professionals about reports of an increased rate of adverse events, including deaths, in clinical trials with the cancer medicine Zydelig (idelalisib) in combination with other cancer medicines.

Gilead Sciences, Inc. has confirmed that they are stopping six clinical trials in patients with chronic lymphocytic leukemia, small lymphocytic lymphoma and indolent non-Hodgkin lymphomas. The FDA is reviewing the findings of the clinical trials and will communicate new information as necessary.

Health care professionals should be aware that Zydelig is not approved for previously untreated chronic lymphocytic leukemia.

Zydelig is currently approved by the FDA for the treatment of:

- Relapsed chronic lymphocytic leukemia, in combination with rituximab, in patients for whom rituximab alone would be considered appropriate therapy due to other co-morbidities.
- Relapsed follicular B-cell non-Hodgkin lymphoma in patients who have received at least two prior systemic therapies.
- Relapsed small lymphocytic lymphoma in patients who have received at least two prior systemic therapies.

Patients should talk to their doctor if they have questions or concerns about Zydelig. The FDA urges health care professionals and patients to report adverse events involving Zydelig to the FDA MedWatch program.

Link: <http://www.fda.gov/Drugs/DrugSafety/ucm490618.htm>

FDA warns consumers about potential risks of using eye drops packaged in bottles with loose safety seals

[Posted: 3/15/16] The U.S. Food and Drug Administration (FDA) is warning the public about eye drop bottles that have loose plastic safety seals or tamper evident rings below the bottle cap that may fall onto the eye when the product is used.

The plastic safety seal or tamper-evident ring, also known as a collar, or band, should stay connected to the bottle neck. However, some eye drop bottles are losing the safety seals or rings when consumers tilt or squeeze the bottle to place eye drops into their eyes. A loose safety seal or ring presents a safety risk as it may cause eye injuries.

Consumers and health care providers who have these products should not attempt to remove the ring or seal because there is a potential to contaminate the tip of the dropper.

FDA is in the process of identifying all relevant products and will require a change in the packaging design. FDA strongly recommends when using tamper-evident rings, the bottle/cap design include a positive-retention mechanism similar to those on disposable plastic beverage bottles to prevent the rings from coming off while using the product.

FDA has received reports of six adverse events associated with loose safety seals on eye drop bottles. Patients and consumers who are using prescription or over the counter eye drops and experience this issue or have concerns should contact their health care provider.

FDA encourages health care providers and consumers to report adverse events to FDA's MedWatch Adverse Event Reporting program:

- Complete and submit the report online at www.fda.gov/medwatch/report.htm; or
- Download and complete the form, then submit it via fax at 1-800-FDA-0178.

FDA is continuing to investigate this issue and will provide more information when it is available.

Link: <http://www.fda.gov/Drugs/DrugSafety/ucm490693.htm>

STUDIES and RECENT TOPICS

FDA designated a record number of orphan drugs last year

February 11, 2016

Orphan drugs may target small patient populations, but they are racking up big numbers at the Food and Drug Administration. Last year, the agency received a record 472 requests from companies to have their medicines designated as orphan drugs. And the FDA agreed to award 354 designations, which was a 22 percent increase over 2014. As for approvals, the agency endorsed 41 orphan medicines, just seven fewer than the previous year, according to the FDA Office of Orphan Products Development. A designation, by the way, means the FDA has decided a drug qualifies for orphan status and takes place before a drug is approved.

Source: <http://www.statnews.com/pharmalot/2016/02/11/fda-designates-record-number-of-orphan-drugs/>

Opioid use may increase infection risk for patients with RA

February 11, 2016

Use of opioid analgesics by patients with rheumatoid arthritis may increase the risk for hospitalization due to serious infection, according to researchers from Vanderbilt University Medical Center.

Source: <http://www.healio.com/rheumatology/rheumatoid-arthritis/news/online/%7Be55284d4-e0d2-4299-8f83-12a71836f2e1%7D/opioid-use-may-increase-infection-risk-for-patients-with-ra>

Merck says U.S. FDA reject its claim that Zetia and Vytorin cut heart risk

February 15, 2016

Drugmaker Merck & Co Inc said the U.S. Food and Drug Administration declined to approve its claim that cholesterol-lowering drugs Zetia and Vytorin reduce the risk of heart attacks and strokes in patients with coronary heart disease.

Source: <http://www.reuters.com/article/merck-co-zetia-fda-idUSL3N15U435>

Gastric reflux drugs may be tied to dementia risk

February 16, 2016

Repeated use of a certain class of drugs for gastric reflux or peptic ulcers was linked with a higher risk for dementia among patients in Germany, researchers say. The drugs, known as proton pump inhibitors (PPIs), include lansoprazole (Prevacid), manufactured by Novartis, as well as esomeprazole (Nexium) and omeprazole (Prilosec), both manufactured by AstraZeneca.

Source: <http://www.reuters.com/article/us-health-dementia-reflux-idUSKCN0VO27I>

More Support for Osteoporosis Drugs

February 15, 2016

Use of osteoporosis drugs, once heavily advertised by celebrity spokeswomen, has dropped by more than 50% in recent years amid reports of such serious side effects as sudden bone fractures. Yet many experts say the benefits of the drugs, known as bisphosphonates, far outweigh the risks for many users.

Source: <http://www.wsj.com/articles/more-support-for-osteoporosis-drugs-1455575920>

Testosterone therapy improves libido but not vitality in older men

February 17, 2016

Men over 64 with low levels of testosterone saw modest improvements in libido and sexual activity when treated with a gel that contains the male hormone, according to U.S. researchers. The treatments did not significantly improve vitality or walking distance in people tested for those problems, according to the results in the New

Source: <http://www.reuters.com/article/us-health-testosterone-elderly-idUSKCN0VQ2YQ>

Prescription drug spending spikes 12 percent, reaching nearly \$300 billion

February 17, 2016

Rise in prescription drug costs a prime driver in notable uptick of overall healthcare spending, CMS says. Prescription drug spending in the United States rose 12 percent in 2014, reaching nearly \$300 billion, the latest issue of the Journal of Managed Care and Specialty Pharmacy showed. That 12 percent figure is backed by a 2015 study by the Office of the Actuary at the Centers for Medicare and Medicaid Services, which claimed that the rise in prescription drug costs is one of the prime drivers of rising healthcare spending.

Source: <http://www.healthcarefinancenews.com/news/prescription-drug-spending-spikes-12-percent-reaching-nearly-300-billion>

Health Buzz: Common Antibiotics May Cause Delirium

February 17, 2016

No, that's not a pink elephant in the hospital room. Delirium and other brain problems have been linked to 54 antibiotics from 12 different classes of drugs, ranging from the commonly used sulfonamides and ciprofloxacin to intravenous cefepime and penicillin, according to a study published Wednesday in Neurology.

Source: <http://health.usnews.com/health-news/health-wellness/articles/2016-02-17/common-antibiotics-may-cause-delirium>

Diabetes Drug May Help Prevent Second Stroke: Study

February 17, 2016

The diabetes drug Actos (pioglitazone) appears to protect people who've already had a stroke from suffering a second stroke, a new study finds. Along with standard treatment after a stroke -- including blood thinners, and blood pressure and cholesterol medication -- the addition of Actos reduced the odds of another stroke by 24 percent compared to a placebo, the researchers said.

Source: <http://consumer.healthday.com/diabetes-information-10/actos-news-795/diabetes-drug-may-help-prevent-second-stroke-708128.html>

Anxiety Drug Overdoses Have Quadrupled Over Last Two Decades, Study Finds

February 18, 2016

More Americans than ever are overdosing on anxiety drugs, researchers reported Thursday — and it's not clear why. The new study finds not only that more Americans are taking the drugs, which include brand names such as Valium and Xanax, but that they're taking more of them.

Source: <http://www.nbcnews.com/health/health-news/anxiety-drug-overdoses-have-quadrupled-over-last-two-decades-study-n521086>

Health officials petition FDA for warning labels on painkillers

February 22, 2016

City and state health directors are urging the Food and Drug Administration (FDA) to put warning labels on powerful painkillers that can be fatal when taken with other drugs. In a petition, a group of health directors led by Dr. Leana Wen, Baltimore's health commissioner, and Dr. Nicole Alexander-Scott, Rhode Island's health director, call for “black box warning” labels on opioids and benzodiazepines.

Source: <http://thehill.com/regulation/healthcare/270313-group-petitions-fda-for-warning-labels-on-painkillers>

HPV Sharply Reduced in Teenage Girls Following Vaccine, Study Says

February 22, 2016

A vaccine introduced a decade ago to combat the sexually transmitted virus that causes cervical cancer has already reduced the virus's prevalence in teenage girls by almost two-thirds, federal researchers said Monday. Even for women in their early 20s, a group with lower vaccination rates, the most dangerous strains of human papillomavirus, or HPV, have still been reduced by more than a third.

Source: http://www.nytimes.com/2016/02/22/health/vaccine-has-sharply-reduced-hpv-in-teenage-girls-study-says.html?_r=2

Most drug makers report incomplete side effects to the FDA

February 23, 2016

The regulatory system for reporting side effects caused by prescription drugs is producing its own kind of side effect — incomplete information about injuries that patients may have suffered. And the reason for the lack of data is that many drug makers are filing patchy reports, according to a new analysis published in the *Pharmacoepidemiology and Drug Safety*.

Source: <http://www.statnews.com/pharmalot/2016/02/23/drug-side-effects-fda/>

Sleeping Pills May Spell Trouble for Older Drivers

February 25, 2016

Older drivers who use the sleeping pill zolpidem, sold widely as Ambien, may have a higher risk of motor vehicle crashes, a new study suggests. Researchers evaluated the five-year driving records of 2,000 Alabama residents, aged 70 and older, comparing those who used the sleeping pill to those who did not. Women who used Ambien had a 61 percent higher probability of a crash over five years compared to nonusers, the study found.

Source: <http://consumer.healthday.com/sleep-disorder-information-33/ambien-news-21/sleeping-pills-can-spell-trouble-for-older-drivers-708346.html>

Providers must inform patients how the prescription drug shortage impacts their care

February 25, 2016

The shortage of prescription drugs in the United States is increasingly placing hospitals, healthcare providers and physicians in the ethical quandary of deciding who will get the antibiotics, cancer drugs or pain medication they need and who will not.

Source: http://www.fiercehealthcare.com/story/providers-must-inform-patients-how-prescription-drug-shortage-impacts-their/2016-02-25?utm_source=hs_email&utm_medium=email&utm_content=26740442&_hsenc=p2ANqtz-_yy7cqVNzvYCEXjDpEhpF2HvPFX3nDuvGoBPBP0kHZFnwsoD4-2GLhdX_wlu7f9Gh0FI0bsAnRWe0_fmESIxSzW3uw8cBqMt0vlvLu9yY1UMDNU&_hsmi=26740442

Tarantula Venom Could Be Used to Create a Powerful Pain Reliever, Scientists Say

February 29, 2016

A spider bite usually results in itching, aching or other pains, but researchers say that venom may someday have a medical use as an effective pain reliever. This week, researchers from Australia presented their early findings on a peptide found in the venom of the Peruvian green velvet tarantula called ProTx-II. Sónia Troeira Henriques, senior research officer at the University of Queensland's Institute for Molecular Bioscience, presented at the Biophysical Society's 60th Annual Meeting currently being held in Los Angeles.

Source: <http://abcnews.go.com/Health/tarantula-venom-create-powerful-pain-reliever-scientists/story?id=37294449>

Waste in Cancer Drugs Costs \$3 Billion a Year, a Study Says

March 1, 2016

The federal Medicare program and private health insurers waste nearly \$3 billion every year buying cancer medicines that are thrown out because many drug makers distribute the drugs only in vials that hold too much for most patients, a group of cancer researchers has found.

Source: http://www.nytimes.com/2016/03/01/health/waste-in-cancer-drugs-costs-3-billion-a-year-a-study-says.html?_r=0

Drug combination slows breast cancer spread

March 2, 2016

A combination of two drugs delays progression of advanced, aggressive breast cancer by an average of nine months - working in all subsets of the most common type of breast cancer. The combination - of a first-in-class targeted drug called palbociclib, and the hormone drug fulvestrant - slowed cancer growth in around two thirds of women with advanced forms of the most common type of breast cancer.

Source: http://www.eurekalert.org/pub_releases/2016-03/iocr-dcs030216.php

Aspirin Is Linked to Lower Risk of Some Cancers

March 3, 2016

Taking aspirin regularly for at least six years was associated with a 19% drop in risk for colon and rectum cancers.

A new study released Thursday finds that aspirin, taken regularly in low doses, is linked to a lower risk

for cancer.

Source: <http://time.com/4246640/aspirin-colorectal-cancer/>

Prenatal and infant paracetamol use independently increase pediatric asthma risk

March 3, 2016

Use of paracetamol during pregnancy and also during infancy could increase the risk for developing asthma in pediatric patients, according to recent research.

Source: <http://www.healio.com/allergy-immunology/asthma-lower-airway-diseases/news/online/%7Bd6e35a97-74ec-4632-b01e-2cc4c26b4925%7D/prenatal-and-infant-paracetamol-use-independently-increase-pediatric-asthma-risk>

ADHD Meds Tied to Lower Bone Density in Kids

March 3, 2016

Children on medications for attention deficit hyperactivity disorder (ADHD) may have lower bone density than their peers, a new U.S. study suggests. Using data from a government health survey, researchers found that children taking ADHD medications had, on average, lower bone density in the hip and lumbar spine (lower back) than kids not on the drugs.

Source: <http://consumer.healthday.com/kids-health-information-23/adderall-news-796/adhd-medications-tied-to-lower-bone-density-in-kids-708434.html>

Earlier intervention with TNF inhibitors seen as more cost-effective for patients with PsA

March 4, 2016

Patients with psoriatic arthritis who had both skin and joint involvement benefited from early use of a tumor necrosis factor inhibitor, but at a higher cost overall. However, costs were lower for some patients who responded quickly to treatment, according to recently presented data.

Source: <http://www.healio.com/rheumatology/psoriatic-arthritis/news/online/%7B48934b50-2adc-454b-9e73-ee3b6469a3ca%7D/earlier-intervention-with-tnf-inhibitors-seen-as-more-cost-effective-for-patients-with-psan>

GSK asthma drug Nucala's long-term study supports safety profile

March 5, 2016

GlaxoSmithKline Plc said on Saturday its asthma drug, Nucala, which is already approved in the United States and Europe, showed a similar safety profile in a long-term study compared with previous studies. GSK said Nucala, which is administered once every four weeks by injection, maintained its risk/benefit profile over an extended 52-week period.

Source: <http://www.reuters.com/article/us-gsk-asthma-idUSKCNOW70RN>

Fluoroquinolones Are Too Risky for Common Infections

March 7, 2016

Last November, Rachel Brummert, 45, of Charlotte, North Carolina, stood before a panel of experts and described the ever-worsening series of health problems, including 10 ruptured tendons and progressive nerve damage, she's suffered as side effects of taking the antibiotic Levaquin, a type of fluoroquinolone, for a suspected sinus infection in 2006.

Source: <http://news.yahoo.com/fluoroquinolones-too-risky-common-infections-140200669.html>

Diet drug Contrave kicks up a tempest amid uncertainty about heart attack and stroke effects

March 8, 2016

Researchers have a gentle warning for patients on the receiving end of 765,000 prescriptions for the weight-loss drug Contrave: The cardiovascular safety of this treatment "remains uncertain," they write in a newly published study.

Source: <http://www.latimes.com/science/sciencenow/la-sci-sn-heart-attack-stroke-diet-drug-contrave-20160308-story.html>

Pregabalin effective in reducing pain, improving sleep in patients with fibromyalgia

March 8, 2016

Pregabalin was effective in reducing pain and improving sleep quality among patients with fibromyalgia through 12 weeks, and adverse effects were consistent with the medication's known safety profile, according to data published in Current Medical Research and Opinion.

Source: <http://www.healio.com/family-medicine/rheumatology/news/online/%7B95651733-4c36-42af->

baf5-ebfc091b255b%7D/pregabalin-effective-in-reducing-pain-improving-sleep-in-patients-with-fibromyalgia

This drug is defying a rare form of leukemia — and it keeps getting pricier

March 9, 2016

When the drug company Novartis launched its breakthrough cancer medicine, Gleevec, in 2001, the list price was \$26,400 a year. The company's chief executive acknowledged it was expensive, calling it an "uphill battle to win understanding for our decision."

Source: https://www.washingtonpost.com/business/this-drug-is-defying-a-rare-form-of-leukemia--and-it-keeps-getting-pricier/2016/03/09/4fff8102-c571-11e5-a4aa-f25866ba0dc6_story.html

Brain Bleed Risk From Warfarin May Be Higher Than Thought

March 9, 2016

The widely used blood thinner warfarin -- also known as Coumadin -- may raise the risk of severe bleeding inside the skull by much more than previously thought, a new study suggests. Researchers examined data from nearly 32,000 U.S. veterans, aged 75 and older, with a common heart rhythm disorder called atrial fibrillation. The investigators found that almost one in three suffered an "intracranial" bleed while taking warfarin for the condition.

Source: <http://consumer.healthday.com/cardiovascular-health-information-20/heart-stroke-related-stroke-353/brain-bleed-risk-from-warfarin-may-be-higher-than-thought-708788.html>

US prescription drug spending increases to an estimated \$457 billion in 2015

March 9, 2016

The report gives some context to the ongoing and tension-filled debate about drug prices in the U.S. It highlights the growing impact of higher-cost specialty drugs and retail price increases on overall spending. "The number of prescriptions is rising, but the majority of the growth in retail drug spending appears to be related to rising prices and changes in the compositions of drugs prescribed—e.g., a general shift toward more expensive prescriptions—rather than changes in the total quantity of prescriptions," the report said.

Source: <http://www.biopharmadive.com/news/us-prescription-drug-spending-increases-to-an-estimated-457-billion-in-201/415315/>

RECALLS*

Product Type	Product Description	Code Info	Class	Reason for Recall	Recalling Firm
CLASS I					
Drugs	CITRULLINE (L) in 25 g, 100 g, 500 g and 1 kg plastic bottles	Lot #: 95482/A, 95482/B, 95482/C, 95482/D, 96453/A, 96453/B, 96453/C, and 96453/D, Exp. 10/31/2014	Class I	Labeling: Label Mix-Up: FDA tested samples of API from Medisca, labeled as to contain L-Citrulline, and results revealed no L-Citrulline was present. Levels of N-acetyl-leucine were found instead.	Medisca Inc 661 State Route 3 Unit C Plattsburgh, NY 12901-6531
Drugs	Akttive High Performance Fat Burner Gold dietary supplement capsules, 30-count bottle	Lot # 000815004400; Exp 12/17	Class I	Marketed Without An Approved NDA/ANDA: Dietary supplements contains undeclared sibutramine, desmethylsibutramine and phenolphthalein based on FDA sampling.	Life and More LLC 5771 NW 112th Ave Apt 112 Doral, FL 33178-4161
Drugs	ACETAMINOPHEN EXTRA-STRENGTH PAIN RELIEVER tablets, 500 mg, 100-count bottle	lot # 45810; Exp. 05/18	Class I	Labeling: Label Error on Declared Strength- Bottles containing 500 mg acetaminophen tablets mislabeled to contain 325 mg tablets.	Medline Industries Inc 1 Medline Pl Mundelein, IL 60060-4485
Drugs	fentaNYL Citrate, Preservative Free, 5 mcg per mL In 0.9% Sodium Chloride, 1 mL Total Volume For IV Use	Lot #: 15002077M, Exp 04-02-2015	Class I	Subpotent Drug	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506
Drugs	fentaNYL Citrate, Preservative Free, 10 mcg per 1 mL In 0.9%	Lot #: 15002250M, Exp 04-02-2015	Class I	Subpotent Drug	Pharmedium Services, LLC

Product Type	Product Description	Code Info	Class	Reason for Recall	Recalling Firm
	Sodium Chloride, 1 mL Total Volume For IV Use				150 N Field Dr Ste 350 Lake Forest, IL 60045-2506
Drugs	Rhino 7 3000, 6 count bottles	All lots	Class I	Marketed without an Approved NDA/ANDA: Products contain undeclared active pharmaceutical ingredients; desmethyl carbondenafil and dapoxetine.	Premiere Sales Group 21446 Golden Triangle Rd Santa Clarita, CA 91350-2911
Drugs	NATUREAL BURN FAT NATURE, 30-count capsules, packaged in clear plastic bottle	All lots	Class I	Marketed Without an Approved NDA/ANDA: Product contains undeclared sibutramine.	Inaffit, LLC 356 Urban Ave Gaithersburg, MD 20878-4054
Drugs	Rhino 7 Platinum 3000, 1 count Blister Pack	All lots	Class I	Marketed without an Approved NDA/ANDA: Products contain undeclared active pharmaceutical ingredients; desmethyl carbondenafil and dapoxetine.	Premiere Sales Group 21446 Golden Triangle Rd Santa Clarita, CA 91350-2911
Drugs	ACETAMINOPHEN REGULAR-STRENGTH PAIN RELIEVER tablets, 325 mg, 100-count bottle.	lot # 45810; Exp. 05/18	Class I	Labeling: Label Error on Declared Strength- Bottles containing 500 mg acetaminophen tablets mislabeled to contain 325 mg tablets.	Medline Industries Inc 1 Medline Pl Mundelein, IL 60060-4485
Drugs	Vitamin Supplement (Vial) D3, (cholecalciferol (vit D3)/lipoic acid/ubiquinol/ methylcobalamin/pyridoxine/methionine/inositol/choline bitartrate	AICACABF@3, AICECABF@2, AJBFCABF@4, ABCCABF@4, AICACABF@5, AICECABF@3,	Class I	Superpotent Drug: The vitamin supplement contains an extremely high level of vitamin	Glades Drugs Inc. 109 S Lake Ave Pahokee, FL 33476-1803

Product Type	Product Description	Code Info	Class	Reason for Recall	Recalling Firm
	USP) capsules, 60, 120 or 180 count vials	AJBHCABF@2, ABCCABF@5, AICBCABF@1, AICECABF@4, AJCBCABF@1, ABGCABF@4, AICBCABF@2, AICECABF@5, JCBCABF@2, BACDCABF@5, AICBCABF@3, AICICABF@3, BAAGCABF@2, BADACABF@3, AICBCABF@4, AJADCABF@1, BAAICABF@1, BACCABF@3, AICECABF@1, AJBECABF@6, BABCCABF@2 and BBAECABF@5, Exp 02/20/2016		D3 (Cholecalciferol)	
Drugs	Ultimate Herbal Slimcap Capsules, 350 mg*, 30-count bottles	Lot #: 05/02/2015 to 05/01/2017	Class I	Marketed Without An Approved NDA/ANDA: product marketed as a dietary supplement was found to be tainted with undeclared sibutramine, a previously approved controlled substance that was removed from the U.S. market in October 2010 for safety reasons, in this tainted product renders it an unapproved drug.	Fit Firm and Fabulous 1504 Lincoln Way Apt 212 Mc Lean, VA 22102-5856
Drugs	Magnesium Sulfate in Water for Injection, (0.325 mEq	Lot: 53-113-JT, Exp 1NOV2016	Class I	Labeling: Incorrect	Hospira Inc. 275 N Field Dr

Product Type	Product Description	Code Info	Class	Reason for Recall	Recalling Firm
	Mg++/mL) 40 mg/mL, 2 g Total, 50 mL Single-Dose			Barcode: Primary bag labeling may be mislabeled with the wrong barcode which scans in as heparin sodium.	Lake Forest, IL 60045-2579
Drugs	APEXXX tablets, 300 mg, packaged in 1-count blister cards	All lots	Class I	Marketed Without An Approved NDA/ANDA: tainted product marketed as a dietary supplement. Product found to be tainted with sildenafil, an FDA approved drug for the treatment of male erectile dysfunction, making this an unapproved drug.	Nuway Distributors, LLC 9020 Pecky Cypress Way Orlando, FL 32836-6562
CLASS II					
Drugs	Haloperidol Oral Solution, USP (Concentrate) 2 mg/mL 15 mL amber bottle	Lot #846881; Exp 01/16	Class II	Defective Container: Confirmed customer complaints of leaking bottles.	Safecor Health, LLC 317 New Boston St Woburn, MA 01801-6231
Drugs	Pramipexole Dihydrochloride Tablets 0.125 mg, 90 Ct Bottles	Lot #: BPA512A; Expiry: 06/2017.	Class II	Presence of Foreign Tablets/Capsules: Presence of a comingled Carbimazole 5 mg tablet.	Macleods Pharma Usa Inc 666 Plainsboro Rd Bldg 200 Ste 230 Plainsboro, NJ 08536-3030
Drugs	Midazolam HCl Syrup, 10 mg/5 mL, 5 mL unit dose cups	Lot: 932333, Exp 08/04/16	Class II	Presence of Foreign Substance: customer complaint that one unit dose cup contained a small	Safecor Health, LLC 317 New Boston St Woburn, MA 01801-6231

Product Type	Product Description	Code Info	Class	Reason for Recall	Recalling Firm
				piece of cardboard contaminant.	
Drugs	SyrSpend SF, Suspending Base	Lot #s: 15J26-U05-027457; 15J26-U05-027473	Class II	Microbial Contamination of Non-Sterile Products: Syrspend SF and Syrspend SF Grape Flavor are being recalled due to the presence of yeast	Fagron, Inc 2400 Pilot Knob Rd Saint Paul, MN 55120-1118
Drugs	SyrSpend SF, Suspending Base	Lot #s: 15A05-U03-022765; 15G29-U03-025975	Class II	Microbial Contamination of Non-Sterile Products: Syrspend SF and Syrspend SF Grape Flavor are being recalled due to the presence of yeast.	Fagron, Inc 2400 Pilot Knob Rd Saint Paul, MN 55120-1118
Drugs	SyrSpend SF, Suspending Base	Lot #s: 15I21-U01-027370; 15I21-U01-026920; 15J19-U05-027406	Class II	Microbial Contamination of Non-Sterile Products: Syrspend SF and Syrspend SF Grape Flavor are being recalled due to the presence of yeast.	Fagron, Inc 2400 Pilot Knob Rd Saint Paul, MN 55120
Drugs	Bupivacaine, 0.25%, 450 mL	All lots	Class II	Lack of Assurance of Sterility: Firm is recalling all unexpired lots of sterile compounded products after FDA inspection found concerns of lack of sterility assurance.	Abbott's Compounding Pharmacy, Inc. 2320 Woolsey St Berkeley, CA 94705-1973
Drugs	calcium elemental, 3 mg/10 mL, 200 mL unit	All lots	Class II	Lack of Assurance of Sterility: Firm is	Abbott's Compounding

Product Type	Product Description	Code Info	Class	Reason for Recall	Recalling Firm
				recalling all unexpired lots of sterile compounded products after FDA inspection found concerns of lack of sterility assurance.	Pharmacy, Inc. 2320 Woolsey St Berkeley, CA 94705-1973
Drugs	Estradiol cypionate/Test cyprionate; 2 mg/50 mg/ml, unit size 5 mL	All lots	Class II	Lack of Assurance of Sterility: Firm is recalling all unexpired lots of sterile compounded products after FDA inspection found concerns of lack of sterility assurance.	Abbott's Compounding Pharmacy, Inc. 2320 Woolsey St Berkeley, CA 94705-1973
Drugs	Folic Acid, 5 mg/mL, 30 mL unit size, refrigerate	All lots	Class II	Lack of Assurance of Sterility: Firm is recalling all unexpired lots of sterile compounded products after FDA inspection found concerns of lack of sterility assurance.	Abbott's Compounding Pharmacy, Inc. 2320 Woolsey St Berkeley, CA 94705-1973
Drugs	Folic Acid, 10 mg/mL, 6 mL unit	All lots	Class II	Lack of Assurance of Sterility: Firm is recalling all unexpired lots of sterile compounded products after FDA inspection found concerns of lack of sterility assurance.	Abbott's Compounding Pharmacy, Inc. 2320 Woolsey St Berkeley, CA 94705-1973
Drugs	Hydroxycobalamine 30 mg/mL, 90 mL unit size	All lots	Class II	Lack of Assurance of Sterility: Firm is recalling all unexpired lots of sterile compounded products after FDA inspection	Abbott's Compounding Pharmacy, Inc. 2320 Woolsey St Berkeley, CA 94705-1973

Product Type	Product Description	Code Info	Class	Reason for Recall	Recalling Firm
				found concerns of lack of sterility assurance.	
Drugs	hydroxyprogesterone in sesame 250 mg/mL, 2 mL, 5 mL, 6 mL, 8 mL unit sizes	All lots	Class II	Lack of Assurance of Sterility: Firm is recalling all unexpired lots of sterile compounded products after FDA inspection found concerns of lack of sterility assurance.	Abbott's Compounding Pharmacy, Inc. 2320 Woolsey St Berkeley, CA 94705-1973
Drugs	hydroxyprogesterone w/ pres; 1 mg/mL, 20 mL unit size	All lots	Class II	Lack of Assurance of Sterility: Firm is recalling all unexpired lots of sterile compounded products after FDA inspection found concerns of lack of sterility assurance.	Abbott's Compounding Pharmacy, Inc. 2320 Woolsey St Berkeley, CA 94705-1973
Drugs	Insulin, 70/30, 10 mL unit size	All lots	Class II	Lack of Assurance of Sterility: Firm is recalling all unexpired lots of sterile compounded products after FDA inspection found concerns of lack of sterility assurance.	Abbott's Compounding Pharmacy, Inc. 2320 Woolsey St Berkeley, CA 94705-1973
Drugs	methylcobalamine 10 mg/mL, 10 mL and 12 mL unit sizes	All lots	Class II	Lack of Assurance of Sterility: Firm is recalling all unexpired lots of sterile compounded products after FDA inspection found concerns of lack of sterility assurance.	Abbott's Compounding Pharmacy, Inc. 2320 Woolsey St Berkeley, CA 94705-1973
Drugs	methylcobalamine 1 mg/mL, 1 mL and 10 mL unit sizes	All lots	Class II	Lack of Assurance of Sterility: Firm is recalling all	Abbott's Compounding Pharmacy, Inc.

Product Type	Product Description	Code Info	Class	Reason for Recall	Recalling Firm
				unexpired lots of sterile compounded products after FDA inspection found concerns of lack of sterility assurance.	2320 Woolsey St Berkeley, CA 94705-1973
Drugs	methylcobalamine 4 mg/mL, 5 mL and 30 mL unit sizes	All lots	Class II	Lack of Assurance of Sterility: Firm is recalling all unexpired lots of sterile compounded products after FDA inspection found concerns of lack of sterility assurance.	Abbott's Compounding Pharmacy, Inc. 2320 Woolsey St Berkeley, CA 94705-1973
Drugs	papaverine prostaglandin 30 mg/30 mcg/mL, 5 mL unit size	All lots	Class II	Lack of Assurance of Sterility: Firm is recalling all unexpired lots of sterile compounded products after FDA inspection found concerns of lack of sterility assurance.	Abbott's Compounding Pharmacy, Inc. 2320 Woolsey St Berkeley, CA 94705-1973
Drugs	progesterone/testosterone (ss oil) 0.25/20 mg/mL, 10 mL unit size	All lots	Class II	Lack of Assurance of Sterility: Firm is recalling all unexpired lots of sterile compounded products after FDA inspection found concerns of lack of sterility assurance.	Abbott's Compounding Pharmacy, Inc. 2320 Woolsey St Berkeley, CA 94705-1973
Drugs	testosterone cypionate, 200 mg/mL, 6 mL and 10 mL unit sizes	All lots	Class II	Lack of Assurance of Sterility: Firm is recalling all unexpired lots of sterile compounded products after FDA inspection found concerns of	Abbott's Compounding Pharmacy, Inc. 2320 Woolsey St Berkeley, CA 94705-1973

Product Type	Product Description	Code Info	Class	Reason for Recall	Recalling Firm
				lack of sterility assurance.	
Drugs	testosterone cypionate, 100 mg/mL, 10 mL unit size	All lots	Class II	Lack of Assurance of Sterility: Firm is recalling all unexpired lots of sterile compounded products after FDA inspection found concerns of lack of sterility assurance.	Abbott's Compounding Pharmacy, Inc. 2320 Woolsey St Berkeley, CA 94705-1973
Drugs	papaverine phent, 25 mg/0.833 mg/mL, 20 mL unit size	All lots	Class II	Lack of Assurance of Sterility: Firm is recalling all unexpired lots of sterile compounded products after FDA inspection found concerns of lack of sterility assurance.	Abbott's Compounding Pharmacy, Inc. 2320 Woolsey St Berkeley, CA 94705-1973
Drugs	Menthocin Patch with Lidocaine-Strong (Menthol 5%, Capsaicin 0.0375%, Methyl Salicylate 20%, Lidocaine 0.5%)	Lot#: 20150326, Exp 03/2018	Class II	Marketed without an approved NDA/ANDA	Bonita Pharmaceuticals, LLC 6380 Commerce Drive Westland, MI 48185-9120
Drugs	TEARS Naturale FREE (dextran 70 and hypromellose 2910) lubricant eye drops, 1% and 0.3%, Preservative Free, 0.9 mL (0.03 FL OZ) Single-Use Vials, packaged in 60-count Single-Use Vials	Lot #: KRJ006, Exp 09/17	Class II	Lack of Assurance of Sterility: Some single-use vials may be filled with water rather than the product solution and the firm cannot guarantee the sterility of the water-filled vials.	Alcon Research, Ltd. 6201 South Fwy Fort Worth, TX 76134-2099
Drugs	Medicated Better Braids, La Laque (salicylic acid) Spray, 2%, 12 FL. OZ. (355 ml.) bottle	Lot #: 9AD5	Class II	Microbial Contamination of a Non-Sterile Products: The product had a positive Staphylococcus aureus test result.	Keystone Laboratories Inc 1103 Kansas St Memphis, TN 38106-1913

Product Type	Product Description	Code Info	Class	Reason for Recall	Recalling Firm
Drugs	Capecitabine tablets USP 500 mg, Cytotoxic Agent, Rx Only, 120 tablets per bottle	Lot # 3A404012V, Exp. 4/2016	Class II	Failed Dissolution: Out of Specification test results (low) at the 18 month time-point.	Teva North America 425 Privet Rd Horsham, PA 19044-1220
Drugs	Baclofen, 2.5 mg/mL INJ, in 100 mL vial	Lot # 07142015#7192@1, Exp 09/12/2015; 09112015#7192@1, Exp 11/10/2015; 10082015#7192@9, Exp 12/07/2015; 11302015#71920@1, Exp 1/30/2015	Class II	Lack of assurance of sterility	TexasStar Pharmacy 3033 W Parker Rd Ste 100 Plano, TX 75023-8000
Drugs	0.9% Sodium Chloride Irrigation, USP, 500 mL bottle	Lot # G120162, Exp 11/18	Class II	PRESENCE OF PARTICULATE MATTER: Product complaint for the presence of particulate matter identified as an insect.	Baxter Healthcare Corp. 1 Baxter Pkwy Deerfield, IL 60015-4625
Drugs	Thyrogen (thyrotropin alfa for injection), 0.9 mg/mL	Lot #: E4029Y02 (carton), E4029 (vial) Exp 09/2016	Class II	Presence of Particulate Matter: Glass particles found in the product after reconstitution.	Genzyme Corporation 500 Kendall Street 675 West Kendall/55 Cambridge Parkway Cambridge, MA 02142-1108
Drugs	Thyrogen (thyrotropin alfa for injection), 0.9 mg/mL after reconstitution, For intramuscular injection	Lot #s: E4029Y03, E4029Y04, E4029Y06, E4029Y07, Exp 12/2017	Class II	Presence of Particulate Matter: Glass particles found in the product after reconstitution.	Genzyme Corporation 500 Kendall Street 675 West Kendall/55 Cambridge Parkway Cambridge, MA 02142-1108
Drugs	Alendronate Sodium Tablets, USP, 70 mg*, 4-count	Lot #s: JKP2234A, JKP2235A, Exp 04/17	Class II	Failed Impurities/Degradation Specifications: Observed levels of highest unknown impurity exceeding specification limit at the 3 month stability time	Sun Pharma Global Fze Office # 43 Block Y Saif Zone Sharm

Product Type	Product Description	Code Info	Class	Reason for Recall	Recalling Firm
				point.	
Drugs	Morphine Sulfate 6 mg/ml/Bupivacaine HCL 32 mg/ml, vol. 22 ml syringe	BUD: 5/3/2016	Class II	Lack of Assurance of Sterility	Hartley Medical Center Pharmacy, Incorporated 113 W Victoria St Long Beach, CA 90805-2162
Drugs	Baclofen 5000 mcg/ml, vol. 20 ml syringe	BUD: 5/3/2016	Class II	Lack of Assurance of Sterility	Hartley Medical Center Pharmacy, Incorporated 113 W Victoria St Long Beach, CA 90805-2162
Drugs	Hydromorphone HCL 10 mg/ml/Baclofen 460 mcg/ml/Bupivacaine HCL, vol. 40 ml	BUD: 5/3/2016	Class II	Lack of Assurance of Sterility	Hartley Medical Center Pharmacy, Incorporated 113 W Victoria St Long Beach, CA 90805-2162
Drugs	Morphine Sulfate 0.5 mg/ml/Baclofen 1000 mcg/ml/, vol. 20 ml syringe	BUD: 5/3/2016	Class II	Lack of Assurance of Sterility	Hartley Medical Center Pharmacy, Incorporated 113 W Victoria St Long Beach, CA 90805-2162
Drugs	Hydromorphone 12 mg/ml/Baclofen 450 mcg/ml, vol. 20 ml, syringe	BUD: 5/3/2016	Class II	Lack of Assurance of Sterility	Hartley Medical Center Pharmacy, Incorporated 113 W Victoria St Long Beach, CA 90805-2162
Drugs	Morphine Sulfate 9 mg/ml/Sufentanil Cit 180 mcg/ml/Bupivacaine HCL 33 mg/ml, vol. 20 ml vial	BUD: 5/3/2016	Class II	Lack of Assurance of Sterility	Hartley Medical Center Pharmacy, Incorporated 113 W Victoria St Long Beach, CA 90805-2162
Drugs	Sufentanil Cit 1000 mcg/ml/Baclofen 300 mcg/ml, vol. 20 ml syringe	BUD: 5/3/2016	Class II	Lack of Assurance of Sterility	Hartley Medical Center Pharmacy, Incorporated 113 W Victoria St Long Beach, CA 90805-2162
Drugs	Morphine Sulfate 0.6 mg/ml, vol. 200 ml syringe	BUD: 5/3/2016	Class II	Lack of Assurance of Sterility	Hartley Medical Center Pharmacy, Incorporated 113 W Victoria St Long Beach, CA 90805-2162
Drugs	Morphine Sulfate 20	BUD: 5/3/2016	Class II	Lack of Assurance	Hartley Medical

Product Type	Product Description	Code Info	Class	Reason for Recall	Recalling Firm
	mg/ml/Bupivacaine HCL 11.3 mg/ml, vol. 40 ml syringe			of Sterility	Center Pharmacy, Incorporated 113 W Victoria St Long Beach, CA 90805-2162
Drugs	Morphine Sulfate 20 mg/ml/Bupivacaine HCL 11.3 mg/ml, vol. 40 ml syringe	BUD: 5/3/2016	Class II	Lack of Assurance of Sterility	Hartley Medical Center Pharmacy, Incorporated 113 W Victoria St Long Beach, CA 90805-2162
Drugs	Hydromorphone HCL 10 mg/ml/Bupivacaine HCL 30 mg/ml, vol. 20 ml syringe	BUD: 5/3/2016	Class II	Lack of Assurance of Sterility	Hartley Medical Center Pharmacy, Incorporated 113 W Victoria St Long Beach, CA 90805-2162
Drugs	Morphine Sulfate 10 mg/ml, vol. 20 ml syringe	BUD: 5/3/2016	Class II	Lack of Assurance of Sterility	Hartley Medical Center Pharmacy, Incorporated 113 W Victoria St Long Beach, CA 90805-2162
Drugs	Baclofen 2000 mcg/ml, vol. 20 ml syringe	BUD: 5/3/2016	Class II	Lack of Assurance of Sterility	Hartley Medical Center Pharmacy, Incorporated 113 W Victoria St Long Beach, CA 90805-2162
Drugs	Hydromorphone HCL 20 mg/ml/Bupivacaine HCL 40 mg/ml, vol. 20 ml syringe	BUD: 5/3/2016	Class II	Lack of Assurance of Sterility	Hartley Medical Center Pharmacy, Incorporated 113 W Victoria St Long Beach, CA 90805-2162
Drugs	Hydromorphone HCL 25 mg/ml, vol. 40 ml syringe	BUD: 5/3/2016	Class II	Lack of Assurance of Sterility	Hartley Medical Center Pharmacy, Incorporated 113 W Victoria St Long Beach, CA 90805-2162
Drugs	Hydromorphone HCL 10 mg/ml/Fentanyl Citrate 0.15 mg/ml, vol. 40 ml syringe	BUD: 5/3/2016	Class II	Lack of Assurance of Sterility	Hartley Medical Center Pharmacy, Incorporated 113 W Victoria St Long Beach, CA 90805-2162
Drugs	Hydromorphone HCL 10 mg/ml, vol. 40 ml syringe	BUD: 5/3/2016	Class II	Lack of Assurance of Sterility	Hartley Medical Center Pharmacy, Incorporated

Product Type	Product Description	Code Info	Class	Reason for Recall	Recalling Firm
					113 W Victoria St Long Beach, CA 90805-2162
Drugs	Morphine Sulfate 1.5 mg/ml, vol. 20 ml syringe	BUD: 5/3/2016	Class II	Lack of Assurance of Sterility	Hartley Medical Center Pharmacy, Incorporated 113 W Victoria St Long Beach, CA 90805-2162
Drugs	Fentanyl Citrate 1.275 mg/ml/Baclofen 150 mcg/ml/Bupivacaine HCL 20 mg/ml/ Clonidine HCL 450 mcg/ml, vol. 40 ml syringe	BUD: 5/3/2016	Class II	Lack of Assurance of Sterility	Hartley Medical Center Pharmacy, Incorporated 113 W Victoria St Long Beach, CA 90805-2162
Drugs	Hydromorphone HCL 1 mg/ml, vol. 22 ml syringe	BUD: 5/3/2016	Class II	Lack of Assurance of Sterility	Hartley Medical Center Pharmacy, Incorporated 113 W Victoria St Long Beach, CA 90805-2162
Drugs	Hydromorphone HCL 25 mg/ml/Bupivacaine HCL 4 mg/ml, vol. 40 ml syringe	BUD: 5/3/2016	Class II	Lack of Assurance of Sterility	Hartley Medical Center Pharmacy, Incorporated 113 W Victoria St Long Beach, CA 90805-2162
Drugs	Hydromorphone HCL 10 mg/ml/Bupivacaine HCL 4 mg/ml, vol. 20 ml syringe	BUD: 5/3/2016	Class II	Lack of Assurance of Sterility	Hartley Medical Center Pharmacy, Incorporated 113 W Victoria St Long Beach, CA 90805-2162
Drugs	Morphine Sulfate 11 mg/ml, vol. 20 ml syringe	BUD: 5/3/2016	Class II	Lack of Assurance of Sterility	Hartley Medical Center Pharmacy, Incorporated 113 W Victoria St Long Beach, CA 90805-2162
Drugs	Hydromorphone HCL 7 mg/ml/Bupivacaine HCL 11.2 mg/ml, vol. 40 ml syringe	BUD: 5/3/2016	Class II	Lack of Assurance of Sterility	Hartley Medical Center Pharmacy, Incorporated 113 W Victoria St Long Beach, CA 90805-2162
Drugs	Sufentanil Cit 200 mcg/ml/Clonidine HCL 1600 mcg/ml, vol. 42 ml syringe	BUD: 5/3/2016	Class II	Lack of Assurance of Sterility	Hartley Medical Center Pharmacy, Incorporated 113 W Victoria St Long Beach, CA

Product Type	Product Description	Code Info	Class	Reason for Recall	Recalling Firm
					90805-2162
Drugs	Sufentanil Cit 200 mcg/ml/Clonidine HCL 1600 mcg/ml, vol. 42 ml syringe	BUD: 5/3/2016	Class II	Lack of Assurance of Sterility	Hartley Medical Center Pharmacy, Incorporated 113 W Victoria St Long Beach, CA 90805-2162
Drugs	Morphine Sulfate 20 mg/ml, vol. 42 ml syringe	BUD: 5/3/2016	Class II	Lack of Assurance of Sterility	Hartley Medical Center Pharmacy, Incorporated 113 W Victoria St Long Beach, CA 90805-2162
Drugs	Morphine Sulfate 0.5 mg/ml, vol. 20 ml syringe	BUD: 5/3/2016	Class II	Lack of Assurance of Sterility	Hartley Medical Center Pharmacy, Incorporated 113 W Victoria St Long Beach, CA 90805-2162
Drugs	Hydromorphone HCL 0.5 mg/ml, vol. 20 ml syringe	BUD: 5/3/2016	Class II	Lack of Assurance of Sterility	Hartley Medical Center Pharmacy, Incorporated 113 W Victoria St Long Beach, CA 90805-2162
Drugs	Sufentanil Cit 50 mcg/ml/Clonidine HCL 1 mcg/ml/Bupivacaine HCL 5 mg/ml, vol. 20 ml syringe	BUD: 5/3/2016	Class II	Lack of Assurance of Sterility	Hartley Medical Center Pharmacy, Incorporated 113 W Victoria St Long Beach, CA 90805-2162
CLASS III					
Drugs	Candesartan Cilexetil Tablets, 16 mg, a) 30 count (NDC 00781-5938-31) and b) 90 count (NDC 00781-5938-92) bottles	a) 3022288 12/2015 3025988 03/2016 3025989 04/2016 3030459 08/2016 3030460 08/2016 3032087 10/2016 3032088 10/2016 3034506 12/2016 3035952 01/2017 3035953 01/2017 b) 3022287 12/2015 3025990 04/2016 3030458 08/2016 3032086 09/2016 3035954 01/2017	Class III	Failed Impurities/Degradation Specifications; 9 month stability timepoint	Sandoz Inc 100 College Rd W Princeton, NJ 08540-6604
Drugs	Paricalcitol Capsules, 1 mcg,	Lot #: C404795,	Class III	Failed	Dr. Reddy's

Product Type	Product Description	Code Info	Class	Reason for Recall	Recalling Firm
	30 capsules per bottle	C404796, C404797, Exp 05/2016; C406272, C406273, C406274, C406518, Exp 07/2016; C409586, C409587, Exp 11/2016; C409588, Exp 12/2016; C501835, C501836, C501837, Exp 02/2017; C503797, C503798, Exp 05/2017; C505009, Exp 06/2017; C505568, C505569, Exp 07/2017		Tablet/Capsule Specifications: Product recalled due to reports of breakage and leakage of Paricalcitol capsules.	Laboratories, Inc. 107 College Rd E Princeton, NJ 08540-6623
Drugs	Paricalcitol Capsules, 2 mcg, 30 capsules per bottle	Lot #s: C404653, C404654, C404655, Exp 05/2016; C505010, Exp 06/2017	Class III	Failed Tablet/Capsule Specifications: Product recalled due to reports of breakage and leakage of Paricalcitol capsules.	Dr. Reddy's Laboratories, Inc. 107 College Rd E Princeton, NJ 08540-6623
Drugs	Paricalcitol Capsules, 4 mcg, 30 capsules per bottle	Lot #s: C404440, Exp 04/2016; C404946, Exp 05/2016; C505704, Exp 07/2017	Class III	Failed Tablet/Capsule Specifications: Product recalled due to reports of breakage and leakage of Paricalcitol capsules.	Dr. Reddy's Laboratories, Inc. 107 College Rd E Princeton, NJ 08540-6623
Drugs	Triamcinolone Diacetate Injectable Suspension, 40 mg/mL, 10mL Multi-Dose Vial for Injection	Lot Number: 12212015@8, Do Not Use Beyond: 03/22/2016, "Compounded on December 21, 2015"	Class III	Labeling: Incorrect or Missing Lot and/or Exp Date: some vials may be mislabeled with an incorrect "Compounded" date, lot number, and "Do Not Use Beyond " date or BUD (Before Use Date) that may be longer than intended.	Isomeric Pharmacy Solution, LLC 2401 S Foothill Dr Salt Lake City, UT 84109-1479

Product Type	Product Description	Code Info	Class	Reason for Recall	Recalling Firm
Drugs	risperiDONE ORALLY DISINTEGRATING TABLETS, 2 mg, 30 Ct Bottles	Lot #: MP4967, Expiry: 04/2016.	Class III	Failed Impurities/Degradation Specifications: Out of specification for a known degradant.	Zyus Pharmaceuticals USA Inc 73 Route 31 N Pennington, NJ 08534-3601
Drugs	Normosol-M and 5% Dextrose (multiple electrolytes and 5% dextrose) Injection Type 1, USP, 1000 mL Single-Dose Container bag	Lot #: 56-853-FW, Exp 01AUG2017	Class III	Labeling: Incorrect or Missing Lot and/or Exp Date: Confirmed customer report of an incorrect expiration date printed on the primary container labeled "01AUG1017" rather than "01AUG2017".	Hospira Inc. 275 N Field Dr Lake Forest, IL 60045-2579
Drugs	sulfur8 medicated LIGHT FORMULA (sulfur) anti-dandruff hair& scalp conditioner, 2%, packaged in a) 2 OZ (57g) jar (UPC 0 75610 43510 8), and b) 4 OZ (113g) jar (UPC 0 75610 43610 5), 1 dozen jars per case, J. Strickland & Co., PO Box 1637, Olive Branch, MS 38654	Lot #: 33UF	Class III	Subpotent Drug: failed at the 3 and 6 month stability time points.	J. Strickland and Co 10420 Desoto Rd Olive Branch, MS 38654-5301
Drugs	Atorvastatin Calcium 10 mg, 10 tablets per blister,100-count package	Lot #GS005602; Exp. 10/15 Lot #GS008855; Exp. 09/17 Lot #GS009074; Exp. 08/17 Lot #GS009393; Exp. 08/17 Lot #GS009760; Exp. 10/17 Lot #GS010599; Exp. 11/17	Class III	Failed Impurities/Degradation Specifications	Golden State Medical Supply Inc. 5187 Camino Ruiz Camarillo, CA 93012-8601
Drugs	Atorvastatin Calcium 20 mg, 10 tablets per blister,100-count package	Lot #GS008856; Exp. 09/17 Lot #GS010268; Exp. 09/17 Lot #GS010600; Exp. 11/17	Class III	Failed Impurities/Degradation Specifications	Golden State Medical Supply Inc. 5187 Camino Ruiz Camarillo, CA 93012-8601
Drugs	Atorvastatin Calcium 40 mg, 10 tablets per blister,100-count package	Lot #GS009075; Exp. 09/17 Lot #GS009763; Exp. 09/17 Lot	Class III	Failed Impurities/Degradation	Golden State Medical Supply Inc. 5187 Camino Ruiz

Product Type	Product Description	Code Info	Class	Reason for Recall	Recalling Firm
		#GS010178; Exp. 10/17		Specifications	Camarillo, CA 93012-8601
Drugs	Atorvastatin Calcium 80 mg, 10 tablets per blister, 100-count package	Lot #GS005603; Exp. 10/15 Lot #GS006691; Exp. 08/17 Lot #GS009073; Exp. 08/17 Lot #GS009395; Exp. 08/17 Lot #GS009764; Exp. 10/17	Class III	Failed Impurities/Degradation Specifications	Golden State Medical Supply Inc. 5187 Camino Ruiz Camarillo, CA 93012-8601
Drugs	Scrub-Stat 4 (chlorhexidine gluconate) Foam Forming Solution, 4%, packaged in a) 800 mL Plastic (HDPE) Bottles	Lot #: a) L041051, Exp 04 /17; L060151, L061951, Exp 06 /17; b) L060151, L061951, Exp 06 /17	Class III	Subpotent drug	Ecolab Inc 370 Wabasha St N Saint Paul, MN 55102-1323

BIOLOGICS

none					
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*Please refer to FDA website for further information; <http://www.fda.gov/Safety/Recalls/EnforcementReports/default.htm>

CURRENT DRUG SHORTAGES

Prochlorperazine Edisylate Injection

February 16, 2016 Products Affected

Reason for the Shortage

- Heritage 5 mg/mL, 2 mL vial, 10 count (NDC 23155-0294-42) Reason for the Shortage Heritage
- Pharmaceuticals states the reason for the shortage was manufacturing delay.

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1063>

Cefotaxime Injection

February 16, 2016

Reason of the Shortage

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

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

Carvedilol Tablets

February 16, 2016

Reason of the Shortage

- Glenmark cannot provide a reason for the shortage.
- Mylan cannot provide a reason for the shortage.
- Sun Pharma cannot provide a reason for the shortage.
- Teva cannot provide a reason for the shortage.

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1208>

Potassium Acetate Injection

February 17, 2016

Reason of the Shortage

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

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

Ofloxacin Otic Solution

February 17, 2016

Reason of the Shortage

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

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1187>

Ethiodized Oil

February 17, 2016

Reason of the Shortage

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

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

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

February 17, 2016

Reason of the Shortage

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

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

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

February 17, 2016

Reason of the Shortage

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

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

Tobramycin Injection

February 22, 2016

Reason of the Shortage

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

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

Milrinone Injection

February 22, 2016

Reason of the Shortage

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

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

Dipyridamole Injection

February 22, 2016

Reason of the Shortage

- West-Ward has dipyridamole injection on shortage due to increased demand.
- Teva's dipyridamole injection has been unavailable since 2010 and the company has no current plans to return the product to market.
- There are no other manufacturers of dipyridamole injection.

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=465>

Dextrose (25%) Injection

February 22, 2016

Reason of the Shortage

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

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1011>

Promethazine Injection

February 24, 2016

Reason of the Shortage

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

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

Ondansetron Injection

February 24, 2016

Reason of the Shortage

- AuroMedics did not provide a reason for the shortage.
- Fresenius Kabi had ondansetron injection on back order due to increased demand.
- Heritage has new NDC numbers for ondansetron injection.
- Hospira has ondansetron injection on shortage due to increased demand.
- Sagent had ondansetron on back order due to increased demand.
- The Medicines Company will no longer be supplying ondansetron.
- West-Ward had ondansetron on back order due to increased demand.
- Wockhardt has ondansetron injection on an FDA import alert

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

Morphine Injections

February 24, 2016

Reason of the Shortage

- Astramorph injection has been unavailable since 2012. Fresenius Kabi changed manufacturing sites and cannot estimate if Astramorph will return.
- Hospira states the shortage is due to manufacturing delays.
- West-Ward launched several new morphine sulfate products in late-September 2015.

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

Meningococcal Vaccines

February 24, 2016

Reason of the Shortage

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

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

Digoxin Injection

February 24, 2016

Reason of the Shortage

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

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

Clindamycin Injection

February 24, 2016

Reason of the Shortage

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

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

Calcium Gluconate Injection

February 24, 2016

Reason of the Shortage

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

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

Acetylcysteine Oral and Inhalation Solution

February 24, 2016

Reason of the Shortage

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

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

Zolpidem Tartrate Immediate Release Tablets

February 25, 2016

Reason of the Shortage

- Aurobindo could not provide a reason for the shortage.
- Major could not provide a reason for the shortage.
- Mylan could not provide a reason for the shortage.
- Torrent was unable to provide availability information.

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

Lorazepam injectable presentations

February 25, 2016

Reason of the Shortage

- Bedford discontinued lorazepam injection in May, 2011 to concentrate on the manufacturing of other products.
- West-Ward has product on shortage due to manufacturing delays.
- Hospira has product on shortage due to manufacturing delays
- Akorn has product available.
- Amphastar has product available.

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

Leucovorin Calcium Injection

February 25, 2016

Reason of the Shortage

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

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

Imipenem Cilastatin Injection

February 25, 2016

Reason of the Shortage

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

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

Flumazenil Injection

February 25, 2016

Reason of the Shortage

- Fresenius Kabi had flumazenil on shortage due to short-term manufacturing delays.
- Mylan Institutional cannot provide a reason for the shortage.
- Sandoz discontinued flumazenil injection in 2015.
- West-Ward states the reason for the shortage is increased demand

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

Dexrazoxane Injection

February 25, 2016

Reason of the Shortage

- Biocodex USA acquired Totect from Apricus Pharmaceuticals in April 2013.
- Mylan Institutional could not provide a 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.

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

Dexamethasone 0.1% Ophthalmic Drops

February 25, 2016

Reason of the Shortage

- Valeant could not provide a reason for the shortage

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1205>

Ceftazidime Injection

February 25, 2016

Reason of the Shortage

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

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

Cefazolin Injection

February 25, 2016

Reason of the Shortage

- BBraun has cefazolin on allocation due to increased demand.
- Fresenius Kabi has cefazolin available.
- WG Critical Care has cefazolin available.
- Sandoz has cefazolin available.
- Hospira has cefazolin available.
- Sagent has cefazolin available

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

Phenytoin Injection

February 26, 2016

Reason of the Shortage

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

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=740>

Vitamin E Aqueous Oral Solution

February 29, 2016

Reason of the Shortage

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

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

Torseamide Injection

February 29, 2016

Reason of the Shortage

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

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

Sufentanil Injection

February 29, 2016

Reason of the Shortage

- West-Ward has sufentanil on shortage due to manufacturing delays
- Hospira has sufentanil on shortage due to manufacturing delays.
- Akorn cannot provide a reason for the shortage.³

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=823>

Retepase Injection

February 29, 2016

Reason of the Shortage

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

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=569>

Mupirocin Calcium 2% Cream

February 29, 2016

Reason of the Shortage

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

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

Morrhuate Sodium Injection

February 29, 2016

Reason of the Shortage

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

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

Liotrix Tablets

February 29, 2016

Reason of the Shortage

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

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

Iron Dextran Injection

February 29, 2016

Reason of the Shortage

- Actavis has INFeD on shortage due to manufacturing delays.
- American Regent's Dexferum injection has been unavailable since 2013.
- Other parenteral iron products are not affected by this shortage.

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

Electrolyte Concentrate

February 29, 2016

Reason of the Shortage

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

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1054>

Dolasetron Mesylate Injection

February 29, 2016

Reason of the Shortage

- Validus Pharmaceuticals acquired Anzemet injection from Sanofi US in December 2015.
- Validus Pharmaceuticals has temporarily discontinued Anzemet 12.5 mg/0.625 mL vials and 500 mg/25 mL vials and cannot state if they will bring these products back to market.

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1230>

Dexpanthenol Injection

February 29, 2016

Reason of the Shortage

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

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

Cefepime Injection

February 29, 2016

Reason of the Shortage

- Apotex could not provide a reason for the shortage.
- BBraun has cefepime on allocation due to increased demand.
- Baxter has cefepime on shortage due to increased demand.
- Fresenius Kabi has cefepime injection on shortage due to manufacturing delays.
- Sagent has cefepime injection on shortage due to manufacturing delays.
- Sandoz discontinued cefepime injection in December 2015.
- WG Critical Care has cefepime injection on shortage due to increased demand.
- Hospira has Maxipime on shortage due to manufacturing delays

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

Ammonium Chloride Injection

February 29, 2016

Reason of the Shortage

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

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

Aminocaproic Acid Injection

February 29, 2016

Reason of the Shortage

- American Regent is not manufacturing aminocaproic acid injection at this time.
- Hospira has aminocaproic acid on shortage due to manufacturing delays.

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=789>

Amino Acid Products

February 29, 2016

Reason of the Shortage

- Baxter was experiencing increased demand.
- BBraun was experiencing increased demand.
- Hospira has amino acid products on back order due to manufacturing delays.

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

Amikacin Injection

February 29, 2016

Reason of the Shortage

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

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

Thiotepa for Injection

March 1, 2016

Reason of the Shortage

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

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

Sterile Empty Vials

March 1, 2016

Reason of the Shortage

- Hospira states the shortage was due to increased demand.
- Fresenius Kabi 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.

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=890>

Propranolol Injection

March 1, 2016

Reason of the Shortage

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

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

Propranolol Hydrochloride Tablets

March 1, 2016

Reason of the Shortage

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

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1189>

Fomepizole Injection

March 1, 2016

Reason of the Shortage

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

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

23.4% Sodium Chloride Concentrated Solution for Injection

March 1, 2016

Reason of the Shortage

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

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

14.6% Sodium Chloride Concentrated Solution for Injection

March 1, 2016

Reason of the Shortage

- Hospira has 14.6% sodium chloride solutions for injection on shortage due to manufacturing delays

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1195>

Sodium Bicarbonate Injection

March 2, 2016

Reason of the Shortage

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

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

Sodium Acetate Injection

March 2, 2016

Reason of the Shortage

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

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

Mitoxantrone Hydrochloride Injection

March 2, 2016

Reason of the Shortage

- Hospira has mitoxantrone injection on shortage due to manufacturing delays.
- Teva has mitoxantrone injection on allocation due to current market conditions.

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1212>

Methylprednisolone Sodium Succinate Injection

March 2, 2016

Reason of the Shortage

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

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

Methylprednisolone Acetate Injection

March 2, 2016

Reason of the Shortage

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

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

Methyldopate Injection

March 2, 2016

Reason of the Shortage

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

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

Levetiracetam Injection

March 2, 2016

Reason of the Shortage

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

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

Leflunomide Tablets

March 2, 2016

Reason of the Shortage

- Apotex has temporarily discontinued leflunomide and cannot state if they will bring the product back to market.
- Heritage states the shortage is due to a delay in obtaining active ingredient.
- Sanofi-Aventis could not provide a reason for the shortage

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

Dibucaine Ointment

March 2, 2016

Reason of the Shortage

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

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

Calcium Chloride Injection

March 2, 2016

Reason of the Shortage

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

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

Ampicillin Injection

March 2, 2016

Reason of the Shortage

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

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1226>

Meropenem Injection

March 3, 2016

Reason of the Shortage

- BBraun had meropenem on shortage due to increased demand.
- Fresenius Kabi states the reason for the shortage was increased demand.
- Hospira has meropenem available. Sandoz discontinued meropenem injection in January 2015.
- AstraZeneca has Merrem on shortage due to increase demand

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=969>

Hydroxyamphetamine Hydrobromide and Tropicamide Ophthalmic Solution

March 3, 2016

Reason of the Shortage

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

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1193>

Ceftriaxone Sodium Injection

March 3, 2016

Reason of the Shortage

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

- Sagent states the reason for the shortage is increased demand.
- Sandoz cannot provide a reason for the shortage.
- WG Critical Care states the reason for the shortage is increased demand.

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

Atropine Sulfate Ophthalmic Solution

March 3, 2016

Reason of the Shortage

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

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

Famotidine Injection

March 4, 2016

Reason of the Shortage

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

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

Calcitriol Injection

March 4, 2016

Reason of the Shortage

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

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=940>

Piperacillin Tazobactam Injection

March 7, 2016

Reason of the Shortage

- Apotex has piperacillin/tazobactam on shortage due to regulatory delays.
- AuroMedics and Sandoz could not provide a reason for the shortage.
- Baxter has Zosyn frozen premixes on allocation due to increased demand.
- Fresenius Kabi has piperacillin/tazobactam on shortage due to increased demand.
- Sagent has piperacillin/tazobactam on shortage due to increased demand.

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

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

Methylphenidate Hydrochloride Chewable Tablets

March 7, 2016

Reason of the Shortage

- Shionogi Pharma has Methylin chewable tablets on shortage due to manufacturing issues.
- Gavis launched methylphenidate chewable tablets in April 2015.

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1163>

Ketorolac Tromethamine Injection

March 7, 2016

Reason of the Shortage

- BD Rx has ketorolac injection available. BD RX is now part of Fresenius Kabi.
- Fresenius Kabi has ketorolac injection available.
- Hospira has ketorolac on shortage due to manufacturing delays for quality improvement activities and increased demand for the product.
- Sagent states the reason for the shortage is demand exceeding supply.
- West-Ward has ketorolac injection on shortage due to manufacturing delays.
- Ben Venue closed its plant in Bedford, Ohio in July 2014.6 FDA imposed an import ban in mid-2013 on several Wockhardt products including ketorolac.
- Sprix Nasal Spray is not affected by this shortage

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

Haemophilus B Conjugate Vaccine

March 7, 2016

Reason of the Shortage

- GlaxoSmithKline cannot provide a reason for the shortage of Hiberix.
- Sanofi Pasteur has ActHIB in short supply due to the shortage of other combination vaccines (eg, Pentacel).
- Merck has PedvaxHIB (Haemophilus b meningococcal protein conjugate vaccine) available.

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

Doxorubicin Injection

March 7, 2016

Reason of the Shortage

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

- Teva has doxorubicin solution for injection available.
- Fresenius Kabi has doxorubicin solution for injection available.
- Caraco has discontinued doxorubicin solution for injection 25 mL and 100 mL vials.
- Pfizer had doxorubicin solution for injection on shortage due to shipping delays.
- Sagent has doxorubicin solution for injection available.
- Mylan cannot provide a reason for the reason for the doxorubicin solution for injection available.
- Actavis has doxorubicin injection available.

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

Cyclopentolate Hydrochloride and Phenylephrine Hydrochloride Ophthalmic Solution

March 7, 2016

Reason of the Shortage

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

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1214>

Tropicamide 1% Ophthalmic Solution

March 8, 2016

Reason of the Shortage

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

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

L-Cysteine Hydrochloride Injection

March 8, 2016

Reason of the Shortage

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

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

Furosemide Injection

March 8, 2016

Reason of the Shortage

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

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

Chlorpromazine Injection

March 8, 2016

Reason of the Shortage

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

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1188>

Vecuronium Bromide Injection

March 9, 2016

Reason of the Shortage

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

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

Tretinoin Oral Capsules

March 9, 2016

Reason of the Shortage

- Par was not able to provide a reason for the shortage.
- Teva was not able to provide a reason for the shortage.

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=838>

Indocyanine Green

March 9, 2016

Reason of the Shortage

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

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

Haloperidol Lactate Injection

March 9, 2016

Reason of the Shortage

- Patriot Pharmaceuticals 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.
- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired several products from Bedford Laboratories in July 2014 including haloperidol lactate injection. West-Ward is not actively marketing haloperidol lactate at this time.
- Janssen could not provide a reason for the shortage.

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

Enalaprilat Injection

March 9, 2016

Reason of the Shortage

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

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=587>

Dexamethasone Sodium Phosphate

March 9, 2016

Reason of the Shortage

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

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

Caffeine and Sodium Benzoate Injection

March 9, 2016

Reason of the Shortage

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

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

Sodium Phosphate Injection

March 10, 2016

Reason of the Shortage

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

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

Indigo Carmine Injection

March 10, 2016

Reason of the Shortage

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

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=861>

Haloperidol Decanoate Injection

March 10, 2016

Reason of the Shortage

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

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

Chloroquine Tablets

March 10, 2016

Reason of the Shortage

- Global Pharmaceuticals discontinued chloroquine tablets in 2014.
- Rising has chloroquine tablets available.
- Ranbaxy has chloroquine tablets on shortage due to third party supply issues.
- West-Ward has chloroquine tablets on shortage due to manufacturing delays.

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

Benzonatate Capsules

March 10, 2016

Reason of the Shortage

- Amneal and Ascend Laboratories cannot provide a reason for the shortage.
- Caraco discontinued benzonatate capsules in mid-2015.
- Zydus states the reason for the shortage is manufacturing delay.
- Pfizer had Tessalon Perles on shortage due to supply and demand issues.
- Vertical discontinued Zonatuss in 2016.

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

Anagrelide Capsules

March 10, 2016

Reason of the Shortage

- Mylan Pharmaceuticals discontinued anagrelide capsules in 2015.
- Teva cannot provide a reason for the shortage

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

Aminocaproic Acid Oral Presentations

March 10, 2016

Reason of the Shortage

- Akorn acquired Versapharm in 2014.
- Akorn stopped distributing and marketing Versapharm's aminocaproic acid product on June 22, 2015.
- Akorn launched Amicar oral solution and 500 mg tablets on June 29, 2015.

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1190>

Thrombin Topical Solution (Bovine)

March 11, 2016

Reason of the Shortage

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

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

Sodium Nitroprusside Injection

March 11, 2016

Reason of the Shortage

- Valeant only has short-dated Nitropress available.

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1223>

Potassium Chloride Injection

March 11, 2016

Reason of the Shortage

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

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

Lidocaine Injection

March 11, 2016

Reason of the Shortage

- Amphastar had lidocaine 2% emergency syringes on shortage due to increase demand for the product.
- AuroMedics introduced lidocaine injection in February 2014.
- Fresenius Kabi has generic lidocaine presentations on shortage due to a supply interruption of API. Xylocaine products are not affected.
- Hospira has lidocaine presentations on shortage due to manufacturing delays and increased demand.

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

Hydralazine Injection

March 11, 2016

Reason of the Shortage

- Akorn did not provide a reason for the hydralazine injection on shortage.
- American Regent has hydralazine injection on shortage due to manufacturing delays.
- Fresenius Kabi has hydralazine injection available.
- X-Gen launched hydralazine injection in September 2015.

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

Cisplatin Injection

March 11, 2016

Reason of the Shortage

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

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

Bupivacaine Injection

March 11, 2016

Reason of the Shortage

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

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

***Please refer to ASHP website for more information**

NEW DRUGS COMING TO MARKET

PRODUCT	MFR	ROUTE	INDICATION	PHARMACOLOGY	MARKET RELEASE
Reslizumab	Teva	IV	Asthma/COPD	Interleukin-5 inhibitor	3/30/2016
emtricitabine/tenofovir alafenamide (F/TAF)	Gilead	Oral	HIV	NNRTI/NRTI	4/7/2016
Ixekizumab	Eli-Lilly	Subcutaneous	Psoriasis, psoriatic arthritis, RA, and axial spondyloarthritis	Targets interleukin-17 receptors	4/23/2016
Nuplazid™ (pimavanserin)	Acadia	Oral	Psychosis associated with parkinson's disease	Selective serotonin inverse agonist	5/1/2016
Obeticholic acid	Intercept	Oral	Primary biliary cirrhosis	Farnesoid-X receptor agonist	5/29/2016
Rociletinib (CO-1686)	Clovis Oncology	Oral	Mutant EGFR T790M NSCLC	Irreversible inhibitor of EGFR	6/28/2016
Zinbryta (daclizumab HYP)	Biogen	Subcutaneous	Multiple sclerosis	Interleukin-2R receptor inhibitor	Q2 2016
Sarilumab	Regeneron/Sanofi	Subcutaneous	RA	Targets interleukin-6r	10/30/2016
Translarna™ (Ataluren)	PTC Therapeutics	Oral	Nonsense mutation Duchenne Muscular Dystrophy and Cystic Fibrosis	Gene transcription modulate, protein restoration	Q4 2016
Brodalumab	Valeant	Subcutaneous	Psoriasis	Interleukin-17 inhibitor	Q4 2016
Andexanet	Pfizer	IV	Anticoagulant reversal	Factor Xa antidote	Q4 2016
Baricitinib	Eli-Lilly	Oral	RA	Janus Kinase-1 and 2 inhibitor	2016
Daclatasvir/Asuna previr/Beclabuvir	Bristol Myers Squibb	Oral	HCV genotype 1	NS5B polymerase inhibitor/ NS5A inhibitor/ protease inhibitor	2016
Buparlisib	Novartis	Oral	2 nd line for metastatic, ER+	Pan-class 1 P13K inhibitor	2016

PRODUCT	MFR	ROUTE	INDICATION	PHARMACOLOGY	MARKET RELEASE
			breast cancer resistant to aromatase inhibitors		
Ztilido (lidocaine patch 1.8%)	Scilex	Topical patch	Post-herpetic neuralgia	Local anesthetic	2016
Lupuzor™ (rigerimod)	ImmunPharma PLC	Subcutaneous	Systemic lupus erythematosus	P140 peptide	2016
Elagolix	Abbvie	Oral	Uterine fibroids and endometriosis	GnRH antagonist	2016
Midostaurin (PKC412)	Novartis	Oral	AML	Kinase inhibitor	2016
Amigal (Migalstat)	Amicus	Oral	Fabry disease	Binds alpha-Gal A	2016
Baxdela (delafloxacin)	Melinta	Oral and IV	Gonorrhea and bacterial skin/soft tissue infections	Fluoroquinolone	2016
Glycopyrronium/formoterol (PT-003)	AstraZeneca	Inhaler	Asthma/COPD	Anticholinergic combination	2016
Eravacycline	Tetraphase	Oral and IV	Complicated UTIs	Noval synthetic tetracycline	2016
MK-8342B	Merck	Vaginal ring	Contraception	Contraceptive	2016
Hydrocodone ER (CEP-33237)	Teva	Oral	Pain	Opioid receptor agonist	2016
Oxycodone/naltrexone ER (ALO-02)	Pfizer	Oral	Pain	Opioid receptor agonist	2016
Ribociclib	Novartis	Oral	HR+, HER2-, postmenopausal advanced breast cancer	CDK4/6 inhibitor	2016
Pacritinib	CTI BioPharma	Oral	Myelofibrosis	Janus Kinase-2/ FMS-like tyrosine kinase-3 inhibitor	2016
Surotomycin	Cubist	Oral	C. diff associated diarrhea	Antibacterial lipopeptide	2016