College of Pharmacy and Pharmaceutical Sciences
WASHINGTON STATE UNIVERSITY

Drug Information Center

Highlights of FDA Activities – 10/1/2020 – 10/31/2020

FDA Drug Safety Communications & Drug Information Updates:

Proposed Hydroxyprogesterone Caproate Injection (Makena) Marketing Withdrawal 10/5/20
The FDA Center for Drug Evaluation and Research proposed that hydroxyprogesterone caproate injection (Makena) be withdrawn from the market after the required postmarket study failed to verify the clinical benefit. The branded product and generic equivalents will remain on the market until the manufacturers decide to remove the product or the FDA Commissioner mandates their removal; however, health care professionals are advised to discuss the benefits, risks, and uncertainties with patients until a final marketing decision is reached.

Insulin Pen Packaging and Dispensing: Drug Safety Communication – Risk of Dispensing Errors and Patient Misuse 10/13/20
The FDA is advising health care professionals to dispense insulin pens to the patient in the original sealed carton to avoid dispensing errors and patients using the wrong product or dose if individual insulin pens are stored or dispensed outside of their carton.

NSAIDs: Drug Safety Communication – Serious Complications in Pregnancy 10/15/20
The FDA is recommending women 20 weeks or later in pregnancy avoid use of NSAIDs because they can cause rare but serious kidney problems in an unborn baby which can lead to low levels of amniotic fluid surrounding the baby and possible complications.

RX-to-OTC Switch Approved: Drug Information Update – Sklice (ivermectin) lotion, 0.5% 10/27/20
The FDA approved the prescription to over-the-counter switch for ivermectin lotion, 0.5% (Sklice, Arbor Pharmaceuticals) for the treatment of head lice in patients 6 months of age and older. Sklice will be marketed in the United States as a nonprescription drug and will no longer be available as a prescription drug.

FDA Publishes List of Essential Medicines, Medical Countermeasures, Critical Inputs Required by Executive Order 10/30/20
FDA published a list of essential medicines, medical countermeasures and critical inputs deemed medically necessary to have available at all times in an amount adequate to serve patient needs and in appropriate dosage forms. The list contains 223 drug and biologic essential medicines and medical countermeasures, as well as 96 device medical countermeasures and will be used to guide efforts to minimize shortages and increase domestic production of the listed products.

Spectrum Infusion Pumps: Urgent Device Correction: Cleaning Practices 10/30/20
The FDA issued a MedWatch safety alert to increase awareness of an urgent device correction distributed by Baxter International regarding cleaning practices for all Spectrum infusion pumps. Deviations from the cleaning methods in the Operator's Manuals has resulted in residue buildup and/or corrosion which has impacted pump operation.

Major Medication/Drug-Related Product Recalls Announced Through MedWatch:

Hand Sanitizer, Ashtel Studios: Recall – Misbranding 10/5/20
Ashtel Studios recalled all lots of hand sanitizer packaged in 0.84-ounce containers because they resembled food and drink pouches labeled with children's characters.

Metformin Hydrochloride Extended Release, Marksans Pharma Limited: Recall – Detection of NDMA 10/5/20
Marksans Pharma Limited expanded their recall of Metformin Hydrochloride ER 500 and 750 mg tablets to an additional 76 lots due to the detection of N-nitrosodimethylamine (NDMA) exceeding the acceptable daily intake. A completed list of recalled lots can be found on the FDA site.

Chlorhexidine Gluconate (GUM Paroex) 0.12% Oral Rinse, Sunstar Americas Inc.: Recall – Microbial Contamination 10/28/20

Sunstar Americas Inc. recalled 13 lots of Chlorhexidine Gluconate (GUM Paroex) 0.12% oral rinse in 4 oz and 16 oz amber bottles bearing an expiration date from 6/30/22 to 9/30/22 to the consumer level due to possible microbial contamination with *Burkholderia lata*. The full list of recalled lots can be found on the FDA site.

Dietary Supplement Recalls & Public Notifications

Notifications were issued regarding active ingredients or contaminants in the following products. Patients are advised not to purchase or use these products.

Product	***Promoted Use***	***Undeclared Ingredient(s) or Contaminants***
Cesium chloride containing products	Cancer	Cesium chloride has not been determined to be safe when used as a dietary supplement

New Product Shortages	***Date Initially Posted***
Cysteamine Hydrochloride Ophthalmic Solution	10/27/20

Product Discontinuations/Withdrawals *(sole source or branded products discontinued)*	***Date Posted***
Metronidazole Tablets 250 mg (Flagyl, Pfizer): 100 and 50 count bottles (NDC: 0025-1831-31, 0025-1831-50); metronidazole tablets remain available from other manufacturers.	10/21/20
Eptifibatide Injection (Integrilin, Merck Sharp and Dohme): remaining strengths discontinued; eptifibatide injection remains available from other manufacturers.	10/21/20
Clindamycin 1% (Cleocin-T 1%, Pfizer): topical solution 60 mL applicator bottle (NDC: 0009-3116-02) and topical gel 30 g and 60 g tubes (NDC: 0009-3331-01, 0009-3331-02); other formulations, strengths and manufacturers for clindamycin remain available.	10/23/20
Medroxyprogesterone Acetate Injection, Suspension (Depo-Provera, Pfizer): 400 mg/mL, 1 carton containing 2.5 mL vial (NDC: 0009-0626-01); medroxyprogesterone acetate injection suspension remains available in other strengths from other manufacturers.	10/27/20
Methocarbamol tablet 750 mg (Robaxin-750, Endo): remains available from other manufacturers	10/27/20
Echothiophate Iodide Ophthalmic Solution (Phospholine Iodide, Pfizer): 6.25 mg package for 0.125% (NDC: 0046-1065-05); patients should be switched to an alternative antiglaucoma agent	10/27/20

New Drug Approvals:	***Description***	***Date Approved***
Atoltivimab, maftivimab, odesivimab-ebgn / Inmazeb / Regeneron Pharmaceuticals	Mixture of three monoclonal antibodies for the treatment of Zaire ebolavirus infection in adult and pediatric patients	10/14/20
Remdesivir / Veklury / Gilead Sciences Inc.	Antiviral for the treatment of COVID-19 requiring hospitalization in adult and pediatric patients 12 years or age and older (see attached drug summary)	10/22/20

New Indications:	***Description***	***Date Approved***
Nivolumab / Opdivo and Ipilimumab / Yervoy / Bristol-Myers Squibb	Use in combination for the first-line treatment of adults with malignant pleural mesothelioma that cannot be removed by surgery	10/2/20
Pitolisant / Wakix / Harmony	Indication expanded to include treatment of cataplexy in patients with narcolepsy	10/13/20
Venetoclax / Venclexta / Abbvie	In combination with azacitidine, decitabine, or low-dose cytarabine for the treatment of newly diagnosed acute myeloid leukemia (AML) in adults 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy	10/16/20

New Dosage Forms or Formulation:	***Description***	***Date Approved***
Ravulizumab-cwvz / Ultomiris / Alexion Pharmaceuticals	Injection: 300 mg/3 mL, 1100 mg/11 mL; higher concentration allows reduced infusion time; the 300 mg/30 mL formulation will be discontinued in mid-2021	10/9/20
Calcipotriene and betamethasone dipropionate / Enstilar / Leo Pharma	Foam: 0.005%/0.064%; for the treatment of plaque psoriasis in adults	10/16/20
Esomeperazole / Dexcel Pharma Technologies Ltd.	Delayed-release orally disintegrating tablets: 20 mg; for treatment of frequent heartburn (occurring 2 or more days a week) in adults (18 years of age and older)	10/20/20
Loteprednol etabonate / Eysuvis / Kala Pharmaceuticals	Ophthalmic suspension: 0.25%; for the short-term (up to two weeks) treatment of signs and symptoms of dry eye disease	10/26/20
Mannitol / Bronchitol / Chiesi USA Inc	Inhalation powder: 40 mg per capsule; for add-on maintenance therapy to improve pulmonary function in adult patients 18 years of age and older with cystic fibrosis. Must pass a tolerance test prior to use.	10/30/20

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Remdesivir / Veklury / Gilead Sciences Inc	
Generic Name / Brand Name / Company	Remdesivir / Veklury / Gilead Sciences Inc
Date of approval	10/22/20
Drug Class (Mechanism of Action if novel agent)	Anti-viral, SARS-CoV-2 nucleotide analog RNA polymerase inhibitor
Indication	Adults and pediatric patients (12 years of age and older and weighing at least 40 kg) for the treatment of coronavirus disease 2019 (COVID-19) requiring hospitalization. Should only be administered in a hospital or healthcare setting providing acute care comparable to inpatient hospital care.
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths. Common Dose/sig	Lyophilized powder for Injection: 100 mg in single-dose vial Injection solution: 100 mg/20 mL in single-dose vial Dose: 200 mg on day 1 followed by once daily maintenance doses of 100 mg from day 2 infused over 30 to 120 minutes. Treatment should be continued for 5 days in patients not requiring mechanical ventilation and/or extracorporeal membrane oxygenation (ECMO) but may be extended to 10 days in such patients if clinical improvement is not observed in 5 days. Recommended treatment duration is 10 days in patients requiring mechanical ventilation and/or ECMO.
DEA Schedule	None
Date of market availability	Available
Similar Medication Names	Remicade, Velcade

Clinical Use Evaluation	
Common Adverse Effects	≥5%: nausea, ALT increased, AST increased
Severe Adverse Effects	Hypersensitivity and infusion related anaphylactic reactions, increased transaminase elevations (ALT and AST), blood alkaline phosphatase increase, heart rate decrease, generalized seizure
Severe Drug-Drug Interactions	Chloroquine phosphate and hydroxychloroquine reduce antiviral activity
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Renal (eGFR) and hepatic laboratory testing and prothrombin time before initiating and during treatment as clinically appropriate.
Used in Pediatric Areas	Approved for use in children 12 years and older weighing 40 kg; safety and efficacy have not been established in patients younger than 12 years or weighing less than 40 kg.
Renal or Hepatic Dosing	Use is not recommended in patients with eGFR less than 30 mL/minute due to potential accumulation of the excipient betadex sulfobutyl ether sodium. Remdesivir pharmacokinetics have not been evaluated in patients with hepatic impairment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindicated in patients with a history of clinically significant hypersensitivity; infusion-related and anaphylactic hypersensitivity reactions have been observed during and following administration. Transaminase elevations have been observed; consider discontinuing remdesivir if ALT increases to greater than 10 times the upper limit of normal or if ALT elevation is accompanied by signs or symptoms of liver inflammation.
Special administration technique or considerations	Must be administered IV infusion over 30 to 120 minutes. Powder requires reconstitution with sterile water prior to diluting in 100 mL or 250 mL 0.9% sodium chloride infusion bag; injection solution requires dilution in 250 mL 0.9% sodium chloride infusion bag. Should be prepared in aseptic conditions and on same day of administration.
Prepared by	Marissa Yocham
Source	Veklury (remdesivir) [prescribing information]. Foster City, CA: Gilead Sciences; October 2020.