Approvals & Updates

June 2023

PharMerica®

New Drug Approvals

Elfabrio (pegunigalsidase alfa-iwxj)

Indication: Fabry disease

Mechanism of Action: Hydrolytic lysosomal neutral glycosphingolipid-specific enzyme

Dosage Form(s): Intravenous injection

Comments: Elfabrio is FDA-approved for treating adults with confirmed Fabray disease. Pre-treatment medications such as antihistamines, antipyretics, and/or corticosteroids may be considered for both enzyme replacement therapy (ERT)-experienced or ERT-naive patients. Cardiopulmonary resuscitation equipment and other appropriate medical support measures should be made readily available during Elfabrio administration. The recommended dosage for Elfabrio is a 1 mg/kg intravenous infusion every 2 weeks. Elfabrio has a boxed warning for hypersensitivity reactions including anaphylaxis and should be discontinued immediately if a severe hypersensitivity reaction occurs. Elfabrio has labeled warnings and precautions for infusion-associated reactions and membranoproliferative glomerulonephritis. The most common adverse reactions (≥15%) reported with Elfabrio are infusion-associated reactions, nasopharyngitis, headache, diarrhea, fatigue, nausea, back pain, pain in extremity, and sinusitis.

Safety Alerts

FDA updates warnings to improve safe use of prescription stimulants used to treat ADHD and other conditions

The FDA recently published updates requiring manufacturers to update the *Boxed Warning* and other important information for prescription stimulants used for the treatment of attention-deficit/hyperactivity disorder (ADHD) and other conditions such as binge-eating disorder and narcolepsy. Examples of common stimulants are Adderall (amphetamine/dextroamphetamine), Concerta (methylphenidate), and Ritalin (methylphenidate). The current prescribing information for prescription stimulants are not consistent in terms of providing up to date warnings about the potential for misuse and abuse that patients often face. Misuse and abuse is when patient's take their own medicine differently than how it was prescribed, sharing their medication with friends and family, or using someone else's medication. Sharing prescription stimulant medication with others can lead to addiction, substance use disorder, overdose, and even death. The risk increases with higher doses or using unapproved methods such as snorting or injecting stimulants. The recommendation for health care professionals are to assess the patient for the risk of misuse, abuse, and addiction prior to prescribing the stimulant, counsel the patient to not share their medication, educate the patient on the proper storage and disposal of any unused medication, and regularly assess the patient throughout treatment for signs and symptoms of nonmedical use.

Creighton University Center for Drug Information & Evidence-Based Practice

Drug Information Consultation Service

Monday through Friday

7:30am-3:30pm Central

1-800-561-3728

Submit your drug information questions HERE

Voicemail service is available after-hours

Epkinly (epcoritamab-bysp)

Indication: Relapsed or refractory diffuse large B-cell lymphoma (DLBCL)

Mechanism of Action: Bispecific CD20-directed CD3 T-cell engager

Dosage Form(s): Subcutaneous injection

Comments: Epkinly is FDA-approved for treating adults with relapsed or refractory DLBCL, including DLBCL arising from indolent lymphoma and high-grade B-cell lymphoma. Administer pre-medications (i.e., prednisolone, dexamethasone, or acetaminophen) and prophylaxis (i.e., *pneumocystis jirovecii pneumonia (PJP) and herpes virus*) vaccines as recommended prior to starting Epkinly. The recommend dose of Epkinly is based on the Cycle and day of treatment; with each cycle lasting 28 days. The recommended doses of Epkinly is as follows: Cycle 1 Day 1 (0.16 mg); Cycle 1 Day 8 (0.8 mg); Cycle 1 Day(s) 15 & 22 (48 mg); Cycle 2 and 3 Day(s) 1, 8, 15, and 22 (48 mg); Cycles 4 to 9 Days(s) 1 & 15 (48 mg); Cycle 10 and beyond Day 1 (48 mg). Hospitalization for at least 24-hours is recommended after the administration of Cycle 1 Day 15 dose. Epkinly 0.16 mg and 0.8 mg need to be diluted prior to administration. Epkinly has a boxed warning for cytokine release syndrome (CR) and immune effector cell-associated neurotoxicity syndrome (ICANS). Epkinly also has labeled warnings and precautions for infections, cytopenias, and embryo-fetal toxicity. The most common adverse reactions (≥20%) reported with Epkinly are CRS fatigue, musculoskeletal pain, injection site reactions, pyrexia, abdominal pain, nausea, and diarrhea. The most common Grade 3 to 4 laboratory abnormalities (≥ 10%) reported with Epkinly are decreases in the following: lymphocyte count, neutrophil count, white blood cell count, hemoglobin, and platelets.

Inpefa (sotagliflozin)

Indication: Heart failure or type 2 diabetes mellitus

Mechanism of Action: Sodium-glucose cotransporter 2 (SGLT2) inhibitor

Dosage Form(s): Oral tablets

Comments: Inpefa is FDA-approved for treating adults heart failure or type 2 diabetes mellitus, chronic kidney disease, and other cardiovascular risk factors and indicated to reduce the risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visits. The recommended dose of Inpefa is 200 mg daily and titrated to 400 mg daily as tolerated. Volume status should be corrected prior to starting Inpefa. Inpefa should only be started in hemodynamically stable decompensated heart failure patients. Inpefa has contraindications for history of serious hypersensitivity reactions. Inpefa has labeled warnings and precautions for diabetic ketoacidosis in patients with type 1 diabetes mellitus and other ketoacidosis, volume depletion, urosepsis and pyelonephritis, hypoglycemia with concomitant use with insulin and insulin secretagogues, necrotizing fasciitis of the perineum (Fournier's Gangrene) and genital mycotic infections. Inpefa is associated with several drug-drug interactions. Monitor digoxin levels if administered with digoxin; monitor clinical status if administered with rifampin; and monitor serum lithium concentrations if administered with lithium. Tin geriatric and renally impaired patients there is a higher incidence of adverse reactions due to volume depletion. The most common adverse reactions (≥5%) reported with Inpefa are urinary tract infection, volume depletion, diarrhea, and hypoglycemia.

Miebo (perfluorhexyloctane)

Indication: Dry eye disease

Mechanism of Action: Semifluorinated alkane

Dosage Form(s): Ophthalmic solution

Comments: Miebo is FDA-approved for treating adults with signs and symptoms of dry eye disease. Patients should remove contact lenses prior to and ≥30 minutes after the administration of Miebo. Miebo is administered as one drop in each affected eye(s) four times daily. There are no labeled contraindications, warnings, or precautions for Miebo. The most common adverse reaction (<4%) reported with Miebo was blurred vision.

Veozah (fezolinetant)

Indication: Moderate to severe vasomotor symptoms due to menopause

Mechanism of Action: Neurokinin 3 (NK3) receptor antagonist

Dosage Form(s): Oral tablets

Comments: Veozah is FDA-approved for treating patients with moderate to severe vasomotor symptoms due to menopause. Baseline bloodwork examining hepatic function and injury should be performed prior to initiation, at 3 months, 6 months, 9 months, and anytime symptoms are indicative of liver injury in patients. The recommended dose of Veozah is to take one 45 mg tablet orally once daily with or without food. Veozah has contraindications for patients with known cirrhosis, severe renal impairment or end-stage renal disease, or with the concomitant use with CYP1A2 inhibitors. Veozah has labeled warnings and precautions for hepatic transaminase elevation. The most common adverse reactions (≥2%) reported with Veozah are abdominal pain, diarrhea, insomnia, back pain, hot flush, and hepatic transaminase elevation.

Xacduro (sulbactam, durlobactam)

Indication: Hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP)

Mechanism of Action: Beta-lactam antibacterial and beta lactamase inhibitor

Dosage Form(s): Intravenous injection

Comments: Xacduro is FDA-approved for treating adults with HABP/VABP caused by pathogens other than susceptible isolates of *Acinetobacter baumanniicalcoaceticus* complex. In patients with a creatinine clearance (ClCr) between 45 to 129 mL/min, Xacduro (1 gram of sulbactam, 1 gram of durlobactam) every 6 hours by intravenous infusion over 3 hours. Dosage adjustments are recommended in patients with a ClCr <45 mL/min and ≥130 mL/min. Xacduro comes as a co-packaged kit containing one clear single-dose vial of sulbactam for injection and two amber single-dose vials of durlobactam for injection. Xacduro is contraindicated in patients with a known history of severe hypersensitivity to its components or other beta-lactam antibacterial drugs. Xacduro has labeled warnings and precautions for hypersensitivity reactions and Clostridioides difficile-associated diarrhea (CDAD). Avoid the concomitant administration with organic anion transporter 1 (OAT1) inhibitors because this may increase the plasma concentrations of Xacduro. The most common adverse reactions (>10%) reported with Xacduro are liver test abnormalities, diarrhea, anemia, and hypokalemia.

Recently Approved Drug Combinations, Dosage Forms/Strengths, Indications, or Biosimilars

Brand (Generic)	Indication	Mechanism of Action	Dosage Form	Comments
Brixadi (buprenorphine)	Opioid use disorder	Partial opioid agonist	Extended-release subcutaneous injection	New dosage form
Motpoly XR (lacosamide)	Partial-onset seizures	Antiepileptic	Extended-release oral capsule	New dosage form
Opvee (nalmefene hydrochloride)	Opioid overdose	Opioid antagonist	Nasal spray	New dosage form
Yuflyma (adalimumab-aaty)	Rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, plaque psoriasis, ankylosing spondylitis, Crohn's disease, ulcerative colitis	Tumor necrosis factor (TNF) blocker	Subcutaneous injection	Biosimilar to Humira