Approvals & Updates

September 2021

PharMerica

New Drug Approvals

Comirnaty (COVID-19 vaccine, mRNA)

Indication: Coronavirus disease 2019 (COVID-19) prophylaxis

Mechanism of Action: Vaccine

Dosage Form(s): Intramuscular (IM) injection

Comments: Comirnaty is FDA-approved for the prevention of COVID-19 due to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in patients ≥16 years old. Comirnaty should be administered IM as a two-dose series (0.3mL/dose) 3 weeks apart. Comirnaty carries labeled warnings for management of acute allergic reactions, myocarditis and pericarditis, syncope, altered immunocompetence, and limitation of effectiveness. Laboratory monitoring is not necessary, and no specific drug interactions were outlined. The most common adverse reactions (≥10%) reported with Comirnaty in patients 16-55 years old were pain at injection site, fatigue, headache, muscle pain, chills, joint pain, fever, and injection site swelling. The most common adverse reactions (≥10%) reported with Comirnaty in patients ≥56 years old were pain at injection site, fatigue, headache, muscle pain, chills, joint pain, injection site swelling, fever, and injection site redness.

Korsuva (difelikefalin)

Indication: Chronic kidney disease-associated pruritis (CKD-aP)

Mechanism of Action: Kappa opioid receptor agonist

Dosage Form(s): Intravenous (IV) injection

Comments: Korsuva is FDA-approved for treating moderate-to-severe CKD-aP in adults on hemodialysis. Korsuva should be administered IV as a 0.5mcg/kg bolus injection into the venous line of the dialysis circuit at the end of each hemodialysis treatment. It must be administered within 1 hour of syringe preparation. Korsuva carries labeled warnings for dizziness, somnolence, mental status changes, and gait disturbances and risk of driving and operating machinery. Laboratory monitoring is not necessary, and clinical studies evaluating Korsuva's drug interaction potential have not been conducted. The most common adverse reactions (≥2% and ≥1% more than placebo) reported with Korsuva were diarrhea, dizziness, nausea, gait disturbances (including falls), hyperkalemia, headache, somnolence, and mental status change.

New Drug Approvals, Continued

Nexviazyme (avalglucosidase alfa-ngpt)

Indication: Pompe disease (lysosomal acid alpha-glucosidase [GAA] deficiency)

Mechanism of Action: Glycogen-specific enzyme

Dosage Form(s): IV injection

Comments: Nexviazyme is FDA-approved for treating late-onset Pompe disease in individuals ≥1 years old. Prior to administration of Nexviazyme, pretreatment with antihistamines, antipyretics, and/or corticosteroids should be considered. Nexviazyme should be administered IV initially at a rate of 1mg/kg/hour. The rate can be gradually increased every 30 minutes following no signs of infusion-associated reactions. Nexviazyme carries a Boxed Warning for severe hypersensitivity reactions, infusion-associated reactions, and risk of acute cardiorespiratory failure in susceptible patients (i.e., patients susceptible to fluid overload or with acute underlying respiratory illness or compromised cardiac respiratory function). Appropriate medical support measures and treatment must be readily available and may need to be utilized along with consideration of immediate discontinuation of Nexviazyme should severe hypersensitivity reactions or infusion-associated reactions occur. Additionally, patients' vitals should be more frequently monitored during Nexviazyme administration if they are at risk for acute cardiorespiratory failure. Nexviazyme has no specific drug interactions outlined. The most common adverse reactions (>5%) reported with Nexviazyme were headache, fatigue, diarrhea, nausea, arthralgia, dizziness, myalgia, pruritus, vomiting, dyspnea, erythema, paresthesia, and urticaria.

Ticovac (tick-borne encephalitis vaccine)

Indication: Tick-borne encephalitis prophylaxis

Mechanism of Action: Vaccine

Dosage Form(s): IM injection

Comments: Ticovac is FDA-approved for preventing tick-borne encephalitis in individuals ≥1 years old. Ticovac should be administered IM as a three-dose primary vaccination as follows based on age:

- 1-15 years old (0.25mL/dose)
    - First dose: Day 0
    - Second dose: 1-3 months after first vaccination
    - Third dose: 5-12 months after second vaccination
- ≥16 years old (0.5mL/dose)
    - First dose: Day 0
    - Second dose: 14 days to 3 months after first vaccination
    - Third dose: 5-12 months after second vaccination

The three-dose vaccine schedule should be finished at least 1 week before potential tick-borne encephalitis virus exposure, and if tick-borne encephalitis virus exposure or re-exposure is anticipated, a booster dose (fourth dose) may be administered at least 3 years following completion of the three-dose vaccine schedule. Ticovac carries labeled warnings for management of acute allergic reactions, altered immunocompetence, human albumin, and limitation of vaccine effectiveness. Ticovac has no specific drug interactions outlined. The most common adverse reactions (>9.1%) reported with Ticovac in patients 1-15 years old were local tenderness, local pain, headache, fever, and restlessness. The most common adverse reactions (>5.1%) reported with Ticovac in patients 16-65 years old were local tenderness, local pain, fatigue, headache, and muscle pain.

Current Drug Shortages

The following shortages have been recently identified by the FDA:

- Atropine sulfate injection
- Sodium acetate injection
- Sodium phosphates injection

For additional information on drug shortages, please contact the Center for Drug Information & Evidence-Based Practice.

New Drug Approvals, Continued

Welireg (belzutifan)

Indication: Von Hippel-Lindau (VHL) disease

Mechanism of Action: Hypoxia-inducible factor-2 alpha inhibitor

Dosage Form(s): Tablets

Comments: Welireg is FDA-approved for treating adults with von Hippel-Lindau disease who need therapy for associated renal cell carcinoma (RCC), central nervous system (CNS) hemangioblastomas, or pancreatic neuroendocrine tumors (pNET) not requiring immediate surgery. Welireg should be administered at the same time each day as 120mg by mouth once daily until progression of disease or unacceptable toxicity. Welireg carries a Boxed Warning for embryo-fetal toxicity, so pregnancy status should be confirmed prior to starting Welireg, and patients should be advised on the need for effective non-hormonal contraception while on Welireg therapy. Welireg carries labeled warnings for anemia and hypoxia. Anemia and hypoxia should be monitored for prior to beginning and periodically throughout therapy. Co-administration of Welireg with UGT2B17 or CYP2C19 inhibitors requires monitoring for anemia and hypoxia and a reduction in the Welireg dose. Co-administration of Welireg with CYP3A4 substrates for which small reductions in concentration can lead to therapeutic failures of the substrates should be avoided. Co-administration of Welireg with hormonal contraceptives may result in breakthrough bleeding or contraceptive failure. The most common adverse reactions (≥25%) reported with Welireg were decreased hemoglobin, anemia, fatigue, increased creatinine, headache, dizziness, increased glucose, and nausea.

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
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