Approvals & Updates

March 2020

Safety Updates

Withdrawal of Weight-Loss Drug Belviq (Lorcaserin)

The FDA recently published a safety communication requesting that the manufacturer of lorcaserin voluntarily withdraw the product from the market due to evidence of an increased incidence of cancer. The manufacturer has complied with this request. Providers should stop prescribing and dispensing lorcaserin, ask patients currently taking lorcaserin to stop therapy, and discuss alternative weight-loss medications or strategies with these patients. No additional cancer screening procedures beyond standard measures are recommended for patients who have taken lorcaserin.

PharMerica

New Drug Approvals

Barhemsys (amisulpride)

Indication: Postoperative nausea and vomiting (PONV)

Mechanism of Action: Dopamine-2 antagonist

Dosage Form: Injection for IV use

Barhemsys is FDA-approved for both the prevention and treatment of PONV in adult patients. For prophylaxis, Barhemsys can be used alone or in combination with an antiemetic of a different class. For treatment, it can be used in patients who have not received prophylaxis or have received prophylaxis with an antiemetic of a different class. The recommended dose, given as an IV infusion over 1-2 minutes, is 5 mg or 10 mg for prophylaxis or treatment, respectively. Barhemsys can cause dose- and concentration-dependent prolongation of the QT interval and thus should be avoided in patients with congenital long QT syndrome and in patients taking droperidol. The most common adverse reactions reported with Barhemsys include abdominal distension, chills, hypokalemia, increased blood prolactin levels, infusion site pain, and procedural hypotension.

New Drug Approvals, Continued

Nexletol (bempedoic acid)

Indication: Heterozygous familial hypercholesterolemia (HeFH) or established atherosclerotic cardiovascular disease (ASCVD)

Mechanism of Action: Adenosine triphosphate-citrate lyase (ACL) inhibitor

Dosage Form: Oral tablets

Nexletol is FDA-approved as an adjunct to diet and maximally tolerated statin therapy for adults with HeFH or established ASCVD. It is given at a dose of 180 mg once daily with or without food. Because Nexletol may cause hyperuricemia, uric acid levels and symptoms of hyperuricemia should be monitored periodically, with urate-lowering drugs initiated as needed. Tendon rupture has been reported in patients taking Nexletol. Thus, it should not be used in patients with a history of tendon disorders and should be discontinued at first sign of tendon rupture. Due to an increased risk for statin-related myopathy, concomitant use of Nexletol with simvastatin and pravastatin should be avoided at doses greater than 20 mg and 40 mg, respectively. The most common adverse reactions reported with Nexletol include upper respiratory tract infection, muscle spasms, hyperuricemia, back pain, abdominal pain, bronchitis, pain in extremity, anemia, and elevated liver enzymes.

Nurtec ODT (rimegepant)

Indication: Migraine treatment

Mechanism of Action: Calcitonin gene-related peptide antagonist

Dosage Form: Orally disintegrating tablets

Nurtec ODT is FDA-approved for the acute treatment of migraine with or without aura in adults. It is taken as a 75 mg dose as needed, with no more than one dose per 24-hour period. While there are no dose adjustments required for renal impairment, its use should be avoided in patients with severe hepatic impairment (Child-Pugh C). Patients using Nurtec ODT should be monitored for hypersensitivity reactions and avoid concomitant use of strong CYP3A4 inhibitors, strong and moderate CYP3A inducers, and inhibitors of P-glycoprotein or BCRP. Patients taking moderate CYP3A4 inhibitors should avoid taking a second dose of Nurtec ODT within 48 hours. The most common adverse reaction reported with Nurtec ODT is nausea.

New Drug Approvals, Continued

Pizensy (lactilol)

Indication: Chronic idiopathic constipation (CIC)

Mechanism of Action: Osmotic laxative

Dosage Form: Oral solution

Pizensy is FDA-approved for the treatment of CIC in adult patients. It is given at an initial dose of 20 grams once daily, with the dose reduced to 10 grams once daily in patients with persistent loose stools. It should be given 2 hours after or 2 hours prior to other oral medications. The use of Pizensy is contraindicated in patients with mechanical gastrointestinal obstruction and galactosemia. The most common adverse reactions reported with Pizensy include upper respiratory tract infection, flatulence, diarrhea, increased blood creatinine phosphokinase, abdominal distension, and increased blood pressure.

Vyepti (eptinezumab-jjmr)

Indication: Migraine prevention

Mechanism of Action: Calcitonin gene-related peptide antagonist

Dosage Form: Injection for IV use

Vyepti is FDA-approved for the prevention of migraine in adults. It is given as a 100 mg dose via IV infusion over 30 minutes every 3 months, with some patients benefiting from a 300 mg dose. Patients receiving Vyepti should be monitored for hypersensitivity reactions. The most common adverse reactions reported with Vyepti include nasopharyngitis and hypersensitivity.

Current Drug Shortages

The following shortages have been recently identified by the FDA:

- Amoxapine tablets
- Fentanyl citrate (Sublimaze) injection

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

Recently Approved Drug Combinations, Dosage Forms, and Biosimilars

Brand (Generic)	Indication	Mechanism of Action	Dosage Form	Comments
Anjeso (Meloxicam)	Moderate to severe pain	NSAID	IV Injection	New dosage form
Nexlizet (Bempedoic acid and ezetimibe)	HeFH or ASCVD	ACL inhibitor (bempedoic acid) and cholesterol absorption inhibitor (ezetimibe)	Oral tablets	New combination
Twirla (Ethinyl estradiol and levonorgestrel)	Contraception	Estrogen (ethinyl estradiol) and progestin (levonorgestrel)	Transdermal system	New dosage form