Approvals & Updates

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PharMerica®

New Drug Approvals

Dojolvi (triheptanoin)

Indication: Long-chain fatty acid oxidation disorders

Mechanism of Action: Medium-chain triglyceride

Dosage Form(s): Oral liquid

Comments: Dojolvi is FDA-approved as a source of calories and fatty acids for treating molecularly confirmed long-chain fatty acid oxidation disorders in pediatric and adult patients. Prior to starting Dojolvi, the patient's daily caloric intake (DCI) should be calculated. For patients not already taking a medium-chain triglyceride product, Dojolvi should be started at about 10% of the patient's DCI divided into at least four doses per day and titrated to the recommended daily dose of up to 35% of the patient's DCI over 2 to 3 weeks, assuming tolerability. Alternatively, patients already taking another medium-chain triglyceride product should discontinue such product prior to beginning Dojolvi. Dojolvi should be administered orally diluted with meals or snacks. If a feeding tube is required, silicone or polyurethane is recommended, as Dojolvi is incompatible with certain plastics (polystyrene, polyvinyl chloride). Dojolvi carries labeled warnings for feeding tube dysfunction and intestinal malabsorption in patients with pancreatic insufficiency. The integrity and functionality of the feeding tube, containers, dosing components, and utensils used to administer Dojolvi should be monitored. Additionally, patients' caloric intake during dose titrations, especially patients with gastrointestinal adverse effects, should be monitored. Concurrent administration of Dojolvi and pancreatic lipase inhibitors should be avoided. The most common adverse reactions (≥10%) reported were abdominal pain, diarrhea, vomiting, and nausea.

New Drug Approvals, Continued

Fintepla (fenfluramine)

Indication: Dravet syndrome-associated seizures

Mechanism of Action: Serotonin 5HT-2 receptor agonist

Dosage Form(s): Oral solution

Comments: Fintepla is FDA-approved for treating Dravet syndrome associated seizures in patients ≥2 years old. The starting and maintenance dose of Fintepla is 0.1 mg/kg orally twice daily, and this can be increased weekly depending on efficacy and tolerability. If patients still require more seizure control, Fintepla can be increased to a maximum maintenance dose of 0.35 mg/kg twice daily (max daily dose of 26 mg); however, if such patients are on concomitant stiripentol and clobazam, the maximum maintenance dose of Fintepla is 0.2 mg/kg twice daily (max daily dose of 17 mg). Fintepla can be administered with or without food, and when discontinued, doses should be tapered down gradually to minimize the risk of increased seizure frequency and status epilepticus. Fintepla has a Boxed Warning for valvular heart disease and pulmonary arterial hypertension. As such, echocardiogram assessments are required before, during, and after Fintepla therapy, and Fintepla is only available through a Risk Evaluation and Mitigation Strategy (REMS) program. Fintepla carries labeled warnings for decreased appetite and weight, somnolence, sedation, and lethargy, suicidal behavior and ideation, withdrawal of antiepileptic drugs, serotonin syndrome, increase in blood pressure, and glaucoma. In addition to monitoring for signs and symptoms associated with all of Fintepla's labeled warnings, as previously mentioned, cardiac monitoring with an echocardiogram is necessary prior to starting, during, and after therapy. Electrocardiograms should be obtained every 6 months during therapy and 3 to 6 months after the last dose of Fintepla. Patients taking stiripentol and clobazam concurrently with Fintepla will require dose adjustments, and an increased Fintepla dose should be considered if taken concurrently with strong CYP1A2 and CYP2B6 inducers or rifampin. The most common adverse reactions (≥10% and greater than placebo) reported were decreased appetite, somnolence, sedation, lethargy, diarrhea, constipation, abnormal echocardiogram, fatigue, malaise, asthenia, ataxia, balance disorder, gait disturbance, blood pressure increased, drooling, salivary hypersecretion, pyrexia, upper respiratory tract infection, vomiting, decreased weight, fall, and status epilepticus.

Uplizna (inebilizumab)

Indication: Neuromyelitis optica spectrum disorder (NMOSD)

Mechanism of Action: CD19-directed cytolytic antibody

Dosage Form(s): Injection

Comments: Uplizna is FDA-approved for treating NMOSD in anti-aquaporin-4 (AQP4) antibody positive adults. Active infection, Hepatitis B virus, quantitative serum immunoglobulins, and tuberculosis screening are required before starting Uplizna. Patients should be premedicated with a corticosteroid, antihistamine, and antipyretic prior to each Uplizna infusion. Further, Uplizna has to be diluted in 250 mL of 0.9% Sodium Chloride Injection before administration. The recommended starting dose is 300 mg intravenously (IV) followed by a second 300 mg IV dose 2 weeks later. Subsequent doses should occur 6 months after the first dose as a single 300 mg IV dose and continue every 6 months thereafter. Doses should be titrated to completion, taking about 90 minutes. Patients should be monitored during and for at least one hour after finishing the infusion. Uplizna carries labeled warnings for infusion reactions, infections, immunoglobulin levels, and fetal risk. Signs and symptoms of infection and progressive multifocal leukoencephalopathy should be monitored, and, as previously mentioned, active infection, Hepatitis B, and tuberculosis screening must occur prior to starting Uplizna. Additionally, quantitative serum immunoglobulins should be monitored, before, during, and after therapy until B-cell repletion. Caution is advised for concomitant administration of Uplizna with immunosuppressant drugs (corticosteroids) due to the potential for increased infection risk. The most common adverse reactions (≥10% and greater than placebo) reported were urinary tract infection and arthralgia.

New Drug Approvals, Continued

Zepzelca (lurbinectedin)

Indication: Small cell lung cancer

Mechanism of Action: Alkylating agent

Dosage Form(s): Injection

Comments: Zepzelca is FDA-approved for treating metastatic small cell lung cancer in adults with disease progression on or after platinum-based chemotherapy. Patients may need to be premedicated with corticosteroids and serotonin antagonists. The recommended dose is 3.2 mg/m^2 IV over 60 minutes every 21 days. Zepzelca carries labeled warnings for myelosuppression, hepatotoxicity, and embryo-fetal toxicity. Liver function tests should be monitored before and during therapy and as clinically indicated. Blood counts should also be monitored before initiating, because Zepzelca should only be administered if baseline neutrophil count is $\geq$1,500 cells/mm^3 and platelet count is $\geq$100,000 /mm^3. Depending on the severity of both monitoring parameters, Zepzelca doses may need to be withheld, reduced, or discontinued. Concomitant administration of Zepzelca with strong or moderate CYP3A inhibitors and inducers should be avoided. The most common adverse reactions and laboratory abnormalities (≥20%) reported with Zepzelca were leukopenia, lymphopenia, fatigue, anemia, neutropenia, increased creatinine, increased alanine aminotransferase, increased glucose, thrombocytopenia, nausea, decreased appetite, musculoskeletal pain, decreased albumin, constipation, dyspnea, decreased sodium, increased aspartate aminotransferase, vomiting, cough, decreased magnesium, and diarrhea.

Current Drug Shortages

The following shortages have been recently identified by the FDA:

- Dexamethasone sodium phosphate injection
- Doxycycline hyclate injection
- Sertraline hydrochloride oral solution
- Timolol maleate ophthalmic solution

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
Gimoti (Metoclopramide)	Diabetic gastroparesis	Dopamine-2 antagonist	Nasal spray	New dosage form
Lyumjev (Insulin lispro-aabc)	Diabetes mellitus (type 1 and 2)	Rapid-acting insulin	Injection	Biosimilar to Humalog
Mycapssa (Octreotide)	Acromegaly	Somatostatin analog	Delayed release capsules	New dosage form
Nyvepria (Pegfilgrastim-apgf)	Chemotherapy-induced neutropenia	Colony-stimulating factor	Injection	Biosimilar to Neulasta
Phesgo (Pertuzumab, trastuzumab, and hyaluronidase-zzxf)	Breast cancer	HER2/neu receptor antagonist and endoglycosidase	Injection	New combination
Semglee (Insulin glargine)	Diabetes mellitus (type 1 and 2)	Long-acting insulin	Injection	Biosimilar to Lantus

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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