Approvals & Updates

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PharMerica

New Drug Approvals

Aphexda (motixafortide)

Indication: Multiple myeloma patients, in combination with filgrastim, to mobilize hematopoietic stem cells to the peripheral blood for collection and autologous transplantation.

Mechanism of Action: Hematopoietic stem cell mobilizer.

Dosage form(s): Subcutaneous injection

Comments: Aphexda is FDA-approved and indicated in combination with filgrastim (G-CSF), in patients with multiple myeloma to mobilize hematopoietic stem cells to the peripheral blood for collection and autologous transplantation. Recommended dosing is 1.25 mg/kg using actual body weight. Aphexda should be initiated after filgrastim has been administered daily for 4 days and 10 to 14 hours prior to initiation of apheresis. A second dose of Aphexda can be administered 10 to 14 hours before a third apheresis. Additionally, Aphexda should be administered via a slow subcutaneous injection, approximately 2 minutes. Injections should be delivered into the abdomen, back or side of the upper arms, or thighs and if more than 1 injection is needed for a single dose, sites should be at least 2 cm apart. All patients will receive premedication (i.e., H1-antihistamine, H2 blocker, and a leukotriene inhibitor) 30 to 60 minutes prior to injection. Analgesic medication can be added and is recommended. Aphexda is contraindicated in patients with a history of serious hypersensitivity reaction to motixafortide. Associated warnings and precautions include anaphylactic shock and hypersensitivity reaction, injection site reactions, tumor cell mobilization, leukocytosis, potential for tumor cell mobilization, and embryo-fetal toxicity. Due to the risk of leukocytosis, white blood cell counts should be monitored during treatment with Aphexda. The most common adverse reactions (≥ 20 %) include injection site reactions, injection site pain, injection site erythema, injection site pruritus, pruritus, flushing, and back pain.

Exxua (gepirone)

Indication: Major depressive disorder

Mechanism of Action: Serotonin modulator

Dosage form(s): Extended-release tablets

Comments: Exxua is FDA-approved for the treatment of major depressive disorder (MDD) in adults. The mechanism of action is not fully understood, however, it is thought to modulate serotonergic activity in the CNS via selective agonist activity at 5HT1A receptors. Recommended dosing of Exxua in adults is 18.2 mg by mouth daily with food and at approximately the same time each day. Dosing may be increased to 36.3 mg daily on Day 4, 54.5 mg daily after Day 7, and 72.6 mg daily after two weeks depending on clinical response and tolerability. Recommended dosing for geriatric, renal impairment (creatine clearance < 50 ml/min), and moderate hepatic impairment (Child-Pugh Class B) patients is 18.2 mg once daily and can be increased to 36.3 mg once daily after one week. Additionally, it is recommended that the Exxua dose be adjusted by 50% when a moderate CYP3A4 inhibitor is administered. Exxua carries a black box warning due to increased risk of suicidal thoughts and behaviors. Patients should be monitored for worsening or emerging thoughts of suicide. Contraindications associated with Exxua include known hypersensitivity to gepirone or any of it's components, prolonged QTc interval > 450 msec at baseline, congenital long QT syndrome, concomitant use of strong CYP3A4 inhibitors, severe hepatic impairment, and use with an MAOI or within 14 days of stopping treatment with Exxua. Warnings and precautions associated with Exxua include QT interval prolongation, serotonin syndrome, and activation of mania/hypomania. Prior to initiation with Exxua, electrolyte abnormalities should be corrected and an electrocardiogram (ECG) performed. ECG's should be performed during dose titration and throughout treatment. The most common adverse reactions ($\geq 5\%$ and twice incidence of placebo) include dizziness, nausea, insomnia, abdominal pain, and dyspepsia.

Ojjaara (momelotinib)

Indication: Myelofibrosis patients with anemia

Mechanism of Action: Kinase inhibitor

Dosage form(s): Tablet

Comments: Ojjaara is FDA-approved to treat intermediate or high-risk myelofibrosis (MF), including primary or secondary (post-polycythemia vera and post-essential thrombocythemia), in adults with anemia. Recommended dosing is 200 mg once daily without regard for food. In patients with severe hepatic impairment (Child-Pugh Class C), Ojjaara starting dose should be decreased to 150 mg once daily. There are no contraindications reported with Ojjaara. Associated warnings and precautions include risk of infections, thrombocytopenia and neutropenia, hepatotoxicity, major adverse cardiovascular events, thrombosis, and malignancies. Patients taking Ojjaara should be monitored for signs and symptoms of infection, thrombosis, cardiovascular events, and development of secondary malignancies. Additionally, liver tests should be obtained prior to and throughout treatment with Ojjaara. The most common adverse reactions ($\geq 20\%$) include thrombocytopenia, hemorrhage, bacterial infection, fatigue, dizziness, diarrhea, and nausea.

Pombiliti (cipaglucosidase alfa-atga)

Indication: Late-onset Pompe disease

Mechanism of Action: Hydrolytic lysosomal glycogen-specific enzyme

Dosage form(s): Intravenous

Comments: Pombiliti is FDA-approved, in combination with Opfolda, to treat late-onset Pompe disease in adult patients weighing ≥ 40 kg and not improving on their current enzyme replacement therapy (ERT). The recommended dosage is 20 mg/kg every other week as an intravenous (IV) infusion over 4 hours. Dosing is calculated using actual body weight. Additional administration recommendations include verifying pregnancy status in patients with reproductive potential, initiating Pombiliti with Opfolda 2 weeks after the last ERT dose, and beginning the Pombiliti infusion one hour after oral administration of Opfolda. The Pombiliti infusion will need to be rescheduled if the infusion cannot be started within 3 hours of Opfolda or the Opfolda dose is missed. Pretreatment with antihistamines, antipyretics, and/or corticosteroids can be considered and is recommended if premedication was used with previous ERT therapy. Pombiliti carries a box warning for hypersensitivity reactions including anaphylaxis, infusion-associated reactions (IARs) and risk of acute cardiorespiratory failure in susceptible patients. Pombiliti should be immediately discontinued in the event of a severe hypersensitivity reaction or IAR. If the hypersensitivity reaction or IAR is mild to moderate, consider holding or slowing the rate of infusion and initiate appropriate medical treatment. Pombiliti is contraindicated in pregnancy and the associated warnings and precautions include embryo-fetal toxicity and risks associated with Opfolda. The most common adverse reactions (≥ 5%) are headache, diarrhea, fatigue, nausea, abdominal pain, and pyrexia.

Rivfloza (nedosiran)

Indication: Decrease urinary oxalate levels in primary hyperoxaluria type 1 patients

Mechanism of Action: LDHA-directed small interfering RNA

Dosage form(s): Subcutaneous injection

Comments: Rivfloza is FDA-approved for adults and children 9 years of age and older with primary hyperoxaluria type 1 (PH1) and relatively preserved kidney function (eGFR ≥ 30 ml/min/1.73m^2) to reduce urinary oxalate levels. Rivfloza should be administered via subcutaneous injection to the abdomen or upper thigh. Recommended dosing is based on both age and actual body weight. In patients ≥ 12 years of age, the recommended dosing for ≥ 50 kg and < 50 kg is 160 mg once monthly and 128 mg once monthly respectively. In children 9 to 11 years of age, recommended dosing for ≥ 50 kg and < 50 kg is 160 mg once monthly and 3.3 mg/kg once monthly (not to exceed 128 mg) respectively. If a dose is missed, it should be administered immediately and dosing schedule resumed from the most recently administered dose. Rivfloza comes in an 80 mg single-dose vial and a 128 mg or 160 mg single-dose pre-filled syringe. Pre-filled syringes are intended for use by healthcare professionals, caregivers, or patients ≥ 12 years of age. Single-use vials are intended for use by healthcare professionals. There are no reported contraindications, warnings, or precautions with Rivfloza. The most common adverse event (≥ 20%) is injection site reactions.

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

Brand (Generic)	Indication	Mechanism of Action	Dosage Form	Comments
Bosulif (Bosutinib)	Adults and pediatrics ≥ 1 year of age with chronic phase Ph+ chronic myelogenous leukemia (CML); adults with accelerated or blast phase PH+ CML.	Kinase inhibitor	Oral capsules	New dosage form
Likmez (metronidazole)	Trichomoniasis in adults; amebiasis in adults and pediatrics; anaerobic bacterial infections in adults	Nitroimidazole antimicrobial	Oral suspension	New dosage form
Ryzumvi (phentolamine)	Pharmacologically-induced mydriasis	Alpha adrenergic blocker	Ophthalmic solution	New dosage form
Technegas (kit for preparation of technetium Tc 99m-labeled carbon inhalation aerosol)	Visualization of pulmonary ventilation; evaluation of pulmonary embolism	Radioactive diagnostic agent	Oral inhalation	New dosage form

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