

NEW DRUG FAX SHEET



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This issue of *New Drug FAX Sheet* briefly reviews topics that include new drug approvals, new drug formulations, and new drug indications. If you need further information, please contact the Center for Healthcare Innovation and Patient Outcomes Research (CHIPOR) at chipor@samford.edu.

NEW DRUG APPROVALS

Etelcalcetide (Parasabiv, Kai Pharms Inc.)

Pharmacology: Calcium-sensing receptor agonist.

Indication: Secondary hyperparathyroidism (HPT) in adult patients with chronic kidney disease (CKD) on hemodialysis.

Adverse Drug Reactions: Decrease in blood calcium, muscle spasms, diarrhea, nausea, vomiting, headache, hypocalcemia, and paresthesia.

Dose: The recommended dose is 5 mg, given by intravenous bolus injection three times weekly at the end of hemodialysis. The maintenance dose is individualized based on parathyroid hormone (PTH) and corrected serum calcium.

Formulation: Injection: 2.5 mg/0.5 mL; 5 mg/mL, or 10 mg/2mL solution in a single-dose vial.

Warnings/Contraindications: Hypocalcemia, worsening heart failure, upper gastrointestinal bleeding; and adynamic bone.

Notes: The dose may be increased in 2.5 mg or 5 mg increments no more frequently than every 4 weeks.

Deflazacort (Emflaza, Marathon Pharmaceuticals, LLC.)

Pharmacology: Corticosteroid.

Indication: Duchenne muscular dystrophy (DMD) in patients 5 years of age and older.

Adverse Drug Reactions: Cushingoid appearance, increases in weight and appetite, upper respiratory tract infection, cough, pollakiuria, hirsutism, central obesity, and nasopharyngitis.

Dose: The recommended dose is 0.9 mg/kg/day administered orally.

Formulation: Tablets: 6 mg, 18 mg, 30 mg, and 36 mg. Oral suspension: 22.75 mg/mL.

Warnings/Contraindications: Alterations in endocrine function and cardiovascular/renal function, increased risk of infection, gastrointestinal perforation, behavioral/mood disturbances, effects on bones, ophthalmic effects, and serious skin rashes.

Notes: If patients are receiving moderate or strong CYP3A4 inhibitors, one third of the recommended dose of deflazacort should be administered.

Telotristat ethyl (Xermelo, Lexicon Pharma Inc.)

Pharmacology: Tryptophan hydroxylase inhibitor.

Indication: Treatment of carcinoid syndrome diarrhea in combination with somatostatin analog (SSA) therapy in adults inadequately controlled by SSA therapy.

Adverse Drug Reactions: Nausea, headache, increased GGT, depression, flatulence, decreased appetite, peripheral edema, and pyrexia.

Dose: 250 mg.

Formulation: Tablets.

Warnings/Contraindications: Constipation.

Notes: Potential for drug-drug interaction with CYP3A4 substrates. The dose of concomitant drugs may need to be increased.

NEW DRUG FORMULATIONS

Ganciclovir (Ganciclovir, Exela Pharma SCS LLC)

Pharmacology: Nucleoside analogue cytomegalavirus (CMV) DNA polymerase inhibitor.

Indication: Treatment of CMV retinitis in immunocompromised adult patients and prevention of CMV disease and transplant recipients at risk for CMV disease.

Dosage form: Injection: 500 mg ganciclovir in 250 mL solution.

Dose: Induction for CMV retinitis / prevention of CMV disease in transplant recipients: 5 mg/kg every 12 hours for 14-21 days.

Dapagliflozin; Saxagliptin (QTern, AstraZeneca)

Pharmacology: Sodium-glucose cotransporter 2 (SGLT-2) inhibitor and dipeptidyl peptidase-4 (DPP-4) inhibitor combination.

Indication: Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus who have inadequate control with either agent alone.

Dosage form: Tablet; 10 mg dapagliflozin / 5 mg saxagliptin.

Dose: Dapagliflozin 10 mg / saxagliptin 5 mg taken orally once daily in the morning with or without food.

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