



<http://www.samford.edu/go/chipor>

Volume 23 (Issue 1)

January 15, 2018

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

Trastuzumab--DKST (Ogivri, Mylan)

Pharmacology: HER2/neu receptor antagonist.

Indication: Treatment of HER2-overexpressing breast cancer, metastatic gastric or gastroesophageal junction adenocarcinoma.

Adverse Drug Reactions: Headaches, diarrhea, nausea, chills, fever, congestive heart failure, insomnia, cough, rash, neutropenia, anemia, stomatitis, weight loss, upper respiratory tract infections, thrombocytopenia, mucosal inflammation, nasopharyngitis, and dysgeusia.

Dose: Dosage varies based on indication (4-8 mg/kg as a 90 minute infusion).

Formulation: 420 mg lyophilized powder in a multiple-dose vial for reconstitution.

Warnings/Contraindications: Exacerbation of chemotherapy-induced neutropenia.

Notes: Pregnancy status of patients should be assessed prior to administration.

Semaglutide (Ozempic, Novo Nordisk)

Pharmacology: Glucagon-like peptide receptor agonist.

Indication: Adjunct to diet and exercise to improve glycemic control in patients with type 2 diabetes.

Adverse Drug Reactions: Nausea, vomiting, diarrhea, abdominal pain and constipation.

Dose: The initial dose is 0.25 mg once weekly; after 4 weeks the dose can be increased to 0.5 mg weekly. The dose can be increased to 1 mg once weekly.

Formulation: Injection in 2 mg/1.5 mL pen.

Warnings/Contraindications: Pancreatitis, diabetic retinopathy complications, hypoglycemia, acute kidney injury, hypersensitivity reactions, etc. Patients should not receive this medication if they have a family history of medullary thyroid carcinomas or in patients with multiple endocrine neoplasia.

Notes: Semaglutide delays gastric emptying and may affect the absorption of other medications.

Ozenoxacin (Xepi, Ferrer Internacional SA)

Pharmacology: Quinolone antimicrobial.

Indication: Topical treatment of impetigo due *Staphylococcus aureus* or *Streptococcus pyogenes* in patients ≥ 2 years.

Adverse Drug Reactions: Rosacea and seborrheic dermatitis.

Dose: Thin layer to the affected area twice daily for up to 5 days.

Formulation: Each gram containing 10 mg ozenoxacin.

Warnings/Contraindications: Overgrowth of nonsusceptible bacteria and fungi.

Notes: Do not use in pediatric patients >2 months old.

Infliximab-qbtx (Ixifi, Pfizer)

Pharmacology: Tumor necrosis factor (TNF) blocker.

Indication: Crohn's disease, ulcerative colitis, rheumatoid arthritis, psoriatic arthritis, and plaque psoriasis.

Adverse Drug Reactions: Infections, infusion-related reactions and abdominal pain.

Dose: Dose varies based on indications. Most indications are administered as 5 mg/5 kg.

Formulation: Lyophilized infliximab containing 100 mg in 15 mL vial for intravenous infusion.

Warnings/Contraindications: Serious infection, invasive fungal infection, malignancies, hepatitis B virus reactivation, hepatotoxicity, heart failures, cytopenias, cardiovascular/cerebrovascular reactions, demyelinating disease, lupus-like syndrome, and live vaccines or therapeutic infectious agents.

Notes: Increased risk of serious infection is observed with coadministration of anakinra or abatacept.

CONTINUED NEXT PAGE

Netarsudil Ophthalmic solution (Rhopressa, Aerie Pharmaceuticals, Inc.)

Pharmacology: Rho kinase inhibitor.

Indication: Reduction of elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension.

Adverse Drug Reactions: Conjunctival hyperemia, corneal verticillata, installation site pain, and conjunctival hemorrhage.

Dose: One drop in the affected eye.

Formulation: Ophthalmic solution containing 0.2 mg/mL of netarsudil.

Warnings/Contraindications: None.

Notes: Twice daily dosing is not recommended.

Ertugliflozin (Steglatro, Merck Sharp Dohme)

Pharmacology: Sodium glucose co-transporter 2 inhibitor.

Indication: Improve glycemic control in adults with type 2 diabetes.

Adverse Drug Reactions: Female genital mycotic infections.

Dose: The starting dose is typically 5 mg once daily.

Formulation: Tablets: 5 and 15 mg.

Warnings/Contraindications: Hypotension.

Notes: More adverse effects occurred when coadministered with drugs that can cause renal impairment.

Ertugliflozin; Sitagliptin (Mylotarg, Pfizer)

Pharmacology: Combination of sodium glucose co-transporter 2 inhibitor and dipeptidase-4 inhibitor.

Indication: Diabetes mellitus.

Adverse Drug Reactions: Female genital mycotic infections.

Dose: 5/100 mg taken in the morning with or without food.

Formulation: Tablets: ertugliflozin 5 mg/sitagliptin 100 mg; ertugliflozin 15 mg/sitagliptin 100 mg.

Warnings/Contraindications: Pancreatitis, hypotension, and ketoacidosis.

Notes: More adverse effects occurred when coadministered with drugs that can cause renal impairment.

Ertugliflozin; Metformin (Segluromet, Merck Sharp Dohme)

Pharmacology: Combination of sodium glucose co-transporter 2 inhibitor and biguanide.

Indication: Type 2 diabetes mellitus.

Adverse Drug Reactions: Female genital mycotic infections, diarrhea, nausea, vomiting flatulence, abdominal discomfort, indigestion, asthenia, and headache.

Dose: Ertugliflozin / metformin-7.5 mg/1000 mg twice daily.

Formulation: Tablets-2.5 mg / 500 mg; 2.5 mg / 1000 mg; 7.5 mg / 500 mg; 7.5 mg/1000 mg.

Warnings/Contraindications: Severe renal impairment; metabolic acidosis; serious hypersensitivity reaction.

Notes: Avoid use in patients with hepatic impairment.

Macimorelin (Macrilen, Aeterna Zentaris GMBH)

Pharmacology: Growth hormone secretagogue receptor agonist.

Indication: Adult growth hormone deficiency.

Adverse Drug Reactions: Dysgesia, dizziness, headache.

Dose: The recommended dose is 0.5 mg/kg after fasting for 8 hours.

Formulation: Oral solution-60 mg.

Warnings/Contraindications: QT prolongation, potential for false positive test results with the use of CYP3A4 inducers; potential for false negative test results; recent onset hypothalamic disease.

Notes: Use with caution with other drugs known to prolong QT interval.

Angiotensin II (Giapreza, La Jolla Pharmaceutical Company)

Pharmacology: Vasoconstrictor.

Indication: Increase blood pressure in adults with septic or distributive shock.

Adverse Drug Reactions: Thromboembolic events.

Dose: Initial dose 20 ng/kg/min. Titrate every 5 minutes by increments of up to 15/mg/kg/min. Maximum dose should not exceed 80 ng/kg/min. Maintenance dose should not exceed 40 ng/kg/min.

Formulation: Injection-2.5 mg/mL and 5 mg/2mL.

Warnings/Contraindications: There is a potential for venous and arterial thromboembolic vents. VTE prophylaxis should be used.

Notes: Use caution when administered with ACE inhibitors.

NEW DRUG FORMULATIONS

Glycopyrrolate (Lonhala Mangnair, Suunovion)

Pharmacology: Anticholinergic.

Indication: Treatment of airflow obstruction in patients with chronic obstructive pulmonary disease.

Dosage form: Inhalation solution. Each 1 mL vial contains 25 mcg of glycopyrrolate.

Dose: Contents of one Lonhala vial twice daily.

Mometasone furoate (Sinuva, Intersect ENT, Inc)

Pharmacology: Corticosteroid-eluting implant.

Indication: Treatment of nasal polyps in patients \geq 18 years of age who have had ethmoid sinus surgery.

Dosage form: Sinus Implant system containing mometasone 1350 mg.

Dose: The implant has to be inserted by an otolaryngologist and can remain in place for over 90 days.

Insulin Lispro (Admelog, Sanofi Aventis US)

Pharmacology: Human insulin analog.

Indication: Type I / II diabetes mellitus.

Dosage form: Injection: 100 units/mL.

Dose: Dosage is individualized based on a variety of factors.

Hydrogen Peroxide (Eskata, Aclaris Therapeutics, Inc.)

Pharmacology: Antiseptic / Disinfectant.

Indication: Treatment of seborrheic keratosis.

Dosage form: Topical solution 40% w/w hydrogen peroxide.

Dose: To be administered via health care provider.

Valsartan (Prexxartan, Carmel Biosciences, Inc.)

Pharmacology: Angiotensin II receptor blocker.

Indication: HTN, CHF, and stable left ventricular hypertrophy.

Dosage form: Oral solution, 4 mg.

Dose: Varies depending on indication.

Bivalirudin Sodium Chloride (Bivalirudin Sodium Chloride, Celerity Pharmaceuticals, LLC)

Pharmacology: Direct thrombin inhibitor.

Indication: Anticoagulant in patients undergoing percutaneous coronary intervention (PCI).

Dosage form: Injection: 250 mg/50 mL; 500 mg/100 mL.

Dose: 0.75 mg/kg IV bolus followed by 1.75 mg/kg/h intravenous infusion for duration of procedure.

Angiotensin II (Giapreza, La Jolla Pharmaceutical Co.)

Pharmacology: Vasoconstrictor.

Indication: Increase blood pressure in adults with shock.

Dosage form: Injection-2.5 mg/L and 5 mg/2 mL.

Dose: 20 ng/kg/min. Titrate every 5 minutes, as needed up to 15 ng/kg/min. Do not exceed 80 ng/kg/min.