



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

Lifitegrast (Xiidra, Shire Development, LLC.)

Pharmacology: Lymphocyte function-associated antigen-1 (LFA-1) antagonist.

Indication: Treatment for the signs and symptoms of dry eye disease (DED).

Adverse Drug Reactions: Instillation site irritation, dysgeusia and decreased visual acuity.

Dose: One drop twice daily in each eye (approximately 12 hours apart).

Formulation: 5% ophthalmic (50 mg/mL) solution.

Warnings/Contraindications: None.

Notes: Contact lenses should be removed and reinserted 15 minutes after administration.

Lixisenatide (Adlyxin, Sanofi-Aventis US, LLC.)

Pharmacology: Glucagon-like peptide -1 (GLP-1) receptor agonist.

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

Adverse Drug Reactions: Nausea, vomiting, headache, diarrhea, dizziness, and hypoglycemia.

Dose: Initiate injection (subcutaneously in the abdomen, thigh, or upper arm) at 10 mcg once daily for 14 days.

Increase the dose to 20 mcg once daily on day 15. Administer once daily within an hour before the first meal of the day.

Formulation: Injection: 50 mcg/mL in 3 mL in green prefilled pen; and 100 mcg/mL in 3mL in burgundy prefilled pen.

Warnings/Contraindications: Anaphylaxis and pancreatitis.

Notes: Lixisenatide may delay gastric emptying of oral medications. Oral medications may be administered 1 hour before or 11 hours after the dose of lixisenatide.

NEW DRUG FORMULATIONS

Dasabuvir, ombitasvir, paritaprevir, and ritonavir (Viekira XR, Abbvie)

Pharmacology: Hepatitis C virus non-nucleoside NS5B polymerase inhibitor, ombitasvir, a hepatitis C virus NS5A inhibitor, paritaprevir, a hepatitis C virus NS3/4A protease inhibitor, and ritonavir, a CYP3A inhibitor.

Indication: Treatment of adult patients with chronic hepatitis C virus (HCV); genotype 1 b infection without cirrhosis or with compensated cirrhosis; or genotype 1a infection without cirrhosis or with compensated cirrhosis for use in combination with ribavirin.

Dosage form: Extended-release tablets: dasabuvir 200 mg, ombitasvir 8.33 mg, paritaprevir 50 mg, and ritonavir 33.33 mg.

Dose: Three tablets taken once daily with a meal.

Riboflavin5'-phosphate in 20% dextran ophthalmic solution (Photrex Viscous, Avedro, Inc.)

Pharmacology: Precursor of two coenzymes, flavin adenine dinucleotide and flavin mononucleotide.

Indication: Use with the KXL system in corneal collagen cross-linking for the treatment of progressive keratoconus and corneal ectasia following refractive surgery.

Dosage form: 3 mL glass syringe containing sterile 1.46 mL riboflavin 5'-phosphate ophthalmic solution.

Dose: Instill one drop on the eye every 2 minutes for 30 minutes. Reassess after 30 minutes.

NEW DRUG INDICATIONS

Dronabinol (Syndros, Insys Development Company, Inc.)

Pharmacology: Cannabinoid.

Indication: Treatment of anorexia associated with weight loss in patients with AIDS; and nausea and vomiting associated with cancer chemotherapy in patients who have failed other antiemetic treatments.

Dose: Anorexia: 2.1 mg orally twice daily, one hour before lunch and dinner. Nausea/vomiting associated with chemotherapy: 4.2 mg/m², administered 1-3 hours prior to chemotherapy and then every 2-4 hours after chemotherapy for a total of 4-6 doses per day. Administer first dose at least 30 minutes prior to eating.

Methylnaltrexone Bromide (Relistor, Salix Pharms)

Pharmacology: Opioid antagonist.

Indication: Treatment of opioid-induced constipation (OIC) in adults with chronic non-cancer pain; methylnaltrexone injection is indicated for treatment of OIC in adults with advanced illness who are receiving palliative care with an insufficient response to laxatives.

Dose: OIC in adult patients with chronic non-cancer pain: 450 mg once daily in the morning; methylnaltrexone injection: 12 mg subcutaneously once daily. OIC in adult patients with advanced illness: pre-filled syringe: 8 or 12 mg.