



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

Volume 21 (Issue 7)

July 18, 2016

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](mailto:chipor@samford.edu).

## NEW DRUG APPROVALS

### **Ga 68 dotatate injection (Netspot, Advanced Accelerator Applications USA, Inc.)**

**Pharmacology:** A radioactive diagnostic agent.

**Indication:** For use with positron emission tomography (PET) for localization of somatostatin receptor positive neuroendocrine tumors (NETs) in adult and pediatric patients.

**Adverse Drug Reactions:** No serious adverse reactions were identified.

**Dose:** 2 MBq/kg of body weight (0.054 mCi/kg) up to 200 MBq (5.4 mCi).

**Formulation:** Supplied as a single dose kit containing: **Vial 1** - (reaction vial with lyophilized powder) containing 40 mcg of dotatate. **Vial 2** - (buffer vial) containing 1 mL of reaction buffer solution.

**Warnings/Contraindications:** Radiation Risk: Contributes to a patient's overall long-term cumulative radiation exposure. Ensure safe handling and preparation procedures to protect patients and health care workers from unintentional radiation exposure. Risk for Image Misinterpretation: The uptake of Ga 68 dotatate can be seen in a variety of tumor types other than NETs (e.g. those derived from neural crest tissue), in other pathologic conditions, and as a normal physiologic variant (e.g. uncinata process of the pancreas).

**Notes:** Breast milk should be pumped and discarded for 12 hours after administration.

### **Nebivolol and Valsartan (Byvalson, Forest Laboratories, LLC)**

**Pharmacology:** A beta-adrenergic blocker and an angiotensin II receptor blocker (ARB).

**Indication:** For the treatment of hypertension.

**Adverse Drug Reactions:** Hypotension and hyperkalemia (>20% increase).

**Dose:** The recommended dose is one nebivolol 5 mg / valsartan 80 mg tablet once daily.

**Formulation:** Tablets containing nebivolol 5 mg and valsartan 80 mg.

**Warnings/Contraindications:** Acute exacerbation of coronary artery disease upon cessation of therapy; Monitor renal function and potassium in susceptible patients. Severe bradycardia, heart block greater than first degree, patients with cardiogenic shock, decompensated cardiac failure, sick sinus syndrome (unless a permanent pacemaker is in place), patients with severe hepatic impairment Child-Pugh >B), hypersensitivity to any component of this product. Do not co-administer nebivolol/valsartan with aliskiren to patients with diabetes.

**Notes:** CYP2D6 enzyme inhibitors increase nebivolol levels. Digitalis glycosides increase the risk of bradycardia. Reserpine or clonidine may produce excessive reduction of sympathetic activity. Can increase serum lithium concentrations and lithium toxicity.

### **Sofosbuvir and Velpatasvir (Epclusa, Gilead Sciences, Inc.)**

**Pharmacology:** A fixed-dose combination of a hepatitis C virus (HCV) nucleotide analog NS5B polymerase inhibitor, and an HCV NS5A inhibitor.

**Indication:** Treatment of adult patients with chronic HCV genotype 1, 2, 3, 4, 5 or 6 infection.

**Adverse Drug Reactions:** Fatigue, anemia, nausea, headache, insomnia and diarrhea.

**Dose:** Sofosbuvir 400mg / and velpatasvir 100 mg.

**Formulation:** One tablet containing sofosbuvir 400 mg and velpatasvir 100 mg.

**Warnings/Contraindications:** Bradycardia may occur in patients taking amiodarone, specifically in patients taking beta blockers, those with cardiac comorbidities, or advanced liver disease. In patients without alternative viable treatment options, cardiac monitoring is recommended.

**Notes:** P-glycoprotein (P-gp) inducers and/or moderate to potent CYP inducers may decrease concentrations of sofosbuvir and/or velpatasvir. Use of sofosbuvir / velpatasvir with P-gp inducers and/or moderate to potent CYP inducers is not recommended.

### **Tetracaine HCl and Oxymetazoline HCl (Kovanaze, St. Renatus LLC)**

**Pharmacology:** An ester local anesthetic (tetracaine HCL) and a vasoconstrictor (oxymetazoline HCL).

**Indication:** Local anesthetic when performing a restorative procedure on Teeth 4-13 and A-J in adults and children who weigh 40 kg or more.

**Adverse Drug Reactions:** Rhinorrhea, nasal congestion, lacrimation increased, nasal discomfort, oropharyngeal pain, transient asymptomatic elevations in systolic blood pressure ( $\geq 25$  mm Hg from baseline) and diastolic blood pressures ( $\geq 15$  mm Hg from baseline).

**Dose:** Adults 2 sprays (0.2 mL per spray), 4 to 5 minutes apart and 1 additional spray (0.2 mL) if adequate anesthesia has not been achieved 10 minutes after the second spray. Children who weigh  $> 40$  kg spray 2 sprays (0.2 mL per spray), 4 to 5 minutes apart.

**Formulation:** Single use nasal spray.

**Warnings/Contraindications:** Caution use in and/ or monitor for: hypertension, thyroid disease; epistaxis, dysphagia, methemoglobinemia, and anaphylactic reactions. Contraindicated if known hypersensitivity to tetracaine, benzyl alcohol, ester local anesthetics, p-aminobenzoic acid (PABA), oxymetazoline, or any component of the product.

**Notes:** Concomitant use of monoamine oxidase inhibitors, nonselective beta adrenergic antagonists, or tricyclic antidepressants may cause hypertension and is not recommended. Discontinue use of oxymetazoline containing products 24 hours prior to kovanaze administration. Avoid concomitant use with intranasal products.

### **Cholera Vaccine (Vaxchora, Pax Vax Bermuda Ltd.)**

**Pharmacology:** Vaccine.

**Indication:** Immunization against disease caused by *Vibrio cholerae* serogroup O1.

**Adverse Drug Reactions:** Tiredness, headache, abdominal pain, nausea/vomiting, lack of appetite, and diarrhea (4%).

**Dose:** 100 mL one-time dose.

**Formulation:** Oral suspension.

**Warnings/Contraindications:** The safety and effectiveness of the cholera vaccine has not been established in immunocompromised persons. Cholera vaccine may be shed in the stool of recipients for at least 7 days. There is a potential for transmission of the vaccine strain to non- vaccinated close contacts. Use caution when considering whether to administer to individuals with immunocompromised close contacts

**Notes:** Do not administer cholera vaccine to patients who have taken oral or parenteral antibiotics within 14 days prior to vaccination. Chloroquine may diminish immune response; therefore, administer cholera vaccine at least 10 days before beginning chloroquine.

## **NEW DRUG FORMULATIONS**

### **Nitroglycerin (Gonitro, G. Pohl Boskamp GmbH & Co. KG)**

**Pharmacology:** A nitrate vasodilator.

**Indication:** Acute relief of an attack or prophylaxis of angina pectoris due to coronary artery disease.

**Dosage form:** Sublingual powder.

**Dose:** One to two 400 mcg packets under the tongue. One additional packet may be administered every 5 minutes as needed.

### **Calcifediol (Rayaldee, Opko Ireland Global Holdings Ltd.)**

**Pharmacology:** A vitamin D3 analog.

**Indication:** Treatment of secondary hyperparathyroidism in adults with stage 3 or 4 chronic kidney disease and serum total 25-hydroxyvitamin D levels less than 30 ng/mL.

**Dosage form:** Extended-release 30 mcg capsules.

**Dose:** 30 mcg once daily

### **Lansoprazole (Lansoprazole, Dexcel Pharma Technologies Ltd.)**

**Pharmacology:** A proton pump inhibitor

**Indication:** Treatment of frequent heartburn.

**Dosage form:** Delayed-release, orally disintegrating tablet.

**Dose:** 15 mg as needed.

Prepared by: Danielle Alexander, Pharm.D. Candidate

Reviewed by Maisha Kelly Freeman, Pharm.D., M.S., BCPS, FASCP