

# 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](mailto:chipor@samford.edu).

## NEW DRUG APPROVALS

### **Plecanatide (Trulance, Synergy Pharms Inc.)**

**Pharmacology:** Guanylate cyclase-C agonist.

**Indication:** Treatment of chronic idiopathic constipation (CIC).

**Adverse Drug Reactions:** Diarrhea ( $\geq 2\%$ ). Other rare ADRs include: sinusitis, upper respiratory tract infection, abdominal distension, flatulence, abdominal tenderness, and increased liver biochemical tests. If severe diarrhea occurs, suspend dosing and rehydrate the patient.

**Dose:** 3 mg taken orally once daily with or without food.

**Formulation:** 3-mg oral tablet.

**Warnings/Contraindications:** Contraindicated in patients less than 6 years of age due to the risk of serious dehydration, and in patients with known or suspected mechanical gastrointestinal obstruction.

**Notes:** Laboratory monitoring is not necessary. Tablets can be crushed and administered in applesauce or with water, or with water via a nasogastric or gastric feeding tube.

## NEW DRUG FORMULATIONS

### **Levocetirizine Dihydrochloride (XYZAL Allergy 24hr, Sanofi-Aventis US)**

**Pharmacology:** Anti-histamine.

**Indication:** Provides temporary relief of the following symptoms due to hay fever or other upper respiratory allergies: runny nose, sneezing, itchy, watery eyes, and itching of the nose or throat.

**Dosage form:** OTC oral tablet; OTC oral solution.

**Dose:** 5 mg; 2.5 mg / 5 mL.

### **Thiotepa (Tepadena, Adienne SA)**

**Pharmacology:** Alkylating agent.

**Indication:** To reduce the risk of graft rejection when used in conjunction with high-dose busulfan and cyclophosphamide as a preparative regimen for allogeneic hematopoietic progenitor (stem) cell transplantation (HSCT) for pediatric patients with class 3 beta-thalassemia.

**Dosage form:** Injection in single-dose vial for reconstitution.

**Dose:** 15 mg / vial; 100 mg / vial.

### **Fluticasone propionate (Armonair Resplick, Teva Pharmaceuticals)**

**Pharmacology:** Respiratory corticosteroid.

**Indication:** Maintenance treatment of asthma as prophylactic therapy in patients 12 years of age and older.

**Dosage form:** Powder for inhalation.

**Dose:** 55 mcg; 113 mcg; 232 mcg per actuation.

## NEW DRUG FORMULATIONS (CONTINUED)

### **Fluticasone propionate and salmeterol (Airduo Resplick, TEVA Pharms)**

Pharmacology: Corticosteroid and a long-acting beta-agonist.

Indication: Treatment of asthma in patients aged 12 years and older.

Dosage form: Powder for inhalation.

Dose: 55 mcg of fluticasone propionate and 14 mcg of salmeterol; 113 mcg of fluticasone propionate and 14 mcg of salmeterol; 232 mcg of fluticasone propionate and 14 mcg of salmeterol per actuation.

### **Ephedrine sulfate (Corphedra, Par Sterile Products)**

Pharmacology: Sympathomimetic; alpha- and beta- adrenergic agonist and a norepinephrine-releasing agent

Indication: Treatment of clinically important hypotension occurring in the setting of anesthesia.

Dosage form: Injection in a single-dose vial.

Dose: 50 mg / mL.

### **Hydrocodone bitartrate (Vantrela ER, TEVA Pharms)**

Pharmacology: Opioid agonist.

Indication: Management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

Dosage form: Extended-release oral tablets.

Dose: 15 mg, 30 mg, 45 mg, 60 mg, and 90 mg.

### **Morphine sulfate (Arymo ER, Egalet Corp)**

Pharmacology: Opioid agonist.

Indication: Management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

Dosage form: Extended-release oral tablets.

Dose: 15 mg. A single dose of ARYMO ER greater than 60 mg, or a total daily dose greater than 120 mg, are only for use in patients in whom tolerance to an opioid of comparable potency has been established.

### **Esbriet (Pirfenidone, Genentech Inc.)**

Pharmacology: Pyridone.

Indication: Idiopathic pulmonary fibrosis.

Dosage form: Oral capsule and oral tablet.

Dose: 267 mg capsule; 801 mg tablet. Take doses with food.

### **Lisdexamfetamine dimesylate (Vyvanse, Shire Dev LLC.)**

Pharmacology: Sympathomimetic; central nervous system (CNS) stimulant.

Indication: Treatment of Attention Deficit Hyperactivity Disorder and the treatment of Binge Eating Disorder.

Dosage form: Chewable oral tablet.

Dose: 10 mg. Maximum dose of 70 mg per day.

## NEW DRUG INDICATIONS

### **Oxymetazoline hydrochloride 1% cream (Rhofade, Allergan Inc.)**

Pharmacology: Alpha<sub>1A</sub> adrenoceptor agonist.

New Indication: Topical treatment of persistent facial erythema associated with rosacea in adults.

Dose: Prime pump bottle before initial use and discard product from first three pumps; tubes do not require priming.

Apply a pea-sized amount once daily in a thin layer to cover the entire face (forehead, nose, each cheek, and chin) avoiding the eyes and lips. Wash hands after application. Each gram of cream contains 10 mg (1%) oxymetazoline hydrochloride, equivalent to 8.8 mg (0.88%) of oxymetazoline free base.