SAMFORD UNIVERSITY GLOBAL DRUG INFORMATION SERVICE'S

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 Samford University Global Drug Information Service at (205) 726-2659.

NEW DRUG APPROVALS

Eluxadine (Viberzi, Actavis)

Pharmacology: Mu opioid receptor agonist.
Indication: Indicated for use in adults with irritable bowel syndrome and concomitant diarrhea.
Adverse Drug Reactions: Constipation, nausea, vomiting, rash, abdominal pain, upper respiratory tract infection, nasopharyngitis, abdominal distention, bronchitis, dizziness, flatulence, increased alanine aminotransferase, fatigue, and viral gastroenteritis were the most common reactions. Symptoms of sedation, somnolence, euphoria, asthma, bronchospasm, respiratory failure, increased aspartate aminotransferase, wheezing, gastroesophageal reflux disease, and feeling drunk were also observed.
Dose: The recommended dose is 100 mg twice daily. Use of 75 mg twice daily is recommended for patients with mild to moderate hepatic impairment, cholecystectomy, concomitant use of an OATP1B1 inhibitor, or those with an inability to tolerate the 100 mg dose.
Formulation: 75-mg and 100-mg tablets.
Warnings/Contraindications: Eluxadine is contraindicated in: bile duct obstruction, sphincter of Oddi dysfunction, alcoholism, consumption of more than 3 alcoholic beverages per day, pancreatitis, pancreatic structural abnormalities, severe hepatic impairment, gastrointestinal obstruction, or a history of severe or chronic constipation. Warnings include sphincter of Oddi spasm and pancreatitis.
Notes: Take with food. Discontinue eluxadine if severe constipation presents for more than 4 days. Inhibition of OATP1B1, CYP1A2, CYP2C8, CYP2C19, CYP3A4, or CYP2D6 may increase eluxadine exposure. Eluxadine may increase the concentration of drugs that are metabolized by CYP3A4 or are substrates of OATP1B1. Constipation is more likely to occur if eluxadine is co-administered with constipation inducing drugs. In animal studies, eluxadine was present in lactating animals but no evidence has been presented to show a risk to either a fetus or infant.

NEW DRUG FORMULATIONS

Hydrocodone Bitartrate; Pseudoephedrine HCl; Guaifenesin (Hycofenix, Mikart)

Pharmacology: Combination consisting of an opioid antitussive, a systemic decongestant, and an expectorant.
Indication: Relief of cough and congestion and to loosen mucous associated with the common cold.
Dosage form: Oral solution of 2.5 mg hydrocodone, 30 mg pseudoephedrine, and 200 mg guaifenesin per 5 mL.
Dose: For patients 18 years or older, take 10 mL every 4-6 hours but do not exceed 4 doses a day.

Hydrocodone Bitartrate; Guaifenesin (Flowtuss, Mikart)

Pharmacology: Combination consisting of an opioid antitussive and an expectorant.
Indication: Relief of cough and to loosen mucous associated with the common cold.
Dosage form: Oral solution of 2.5 mg hydrocodone and 200 mg guaifenesin per 5 mL.
Dose: For patients 18 years or older, take 10 mL every 4-6 hours but do not exceed 6 doses a day.

Insulin Lispro (Humalog KwikPen, Eli Lilly and Co)

Pharmacology: Rapid acting insulin.
Indication: Maintain glycemic control in patients with diabetes mellitus.
Dosage form: Prefilled injectable pen containing insulin lispro at 200 units/mL.
Dose: Dosing is patient specific and dependent on the unique needs of the patient.

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Paliperidone Palmitate (Invega Trinza, Janssen Pharms)
Pharmacology: Atypical antipsychotic.
Indication: Maintenance treatment of schizophrenia in patients that have been successfully treated on the monthly formulation of paliperidone palmitate (Invega Sustenna) for at least 4 months.
Dosage form: Prefilled syringe containing an extended release injectable suspension of 273 mg, 410 mg, 546 mg, or 819 mg.
Dose: Dosing is dependent on the last month's intramuscular paliperidone palmitate (Invega Sustenna) injection dose. The dosing schedule is below.

LAST DOSE OF INVEGA SUSTENNA:	INITIATE INVEGA TRINZA AT THE FOLLOWING DOSE:
78 mg	273 mg
117 mg	410 mg
156 mg	546 mg
234 mg	819 mg

Sumatriptan; Naproxen (Treximet, Pernix Ireland LTD)
Pharmacology: Combination of a serotonergic receptor agonist and a non-steroidal anti-inflammatory drug.
Indication: Treatment of migraines with or without aura in pediatric patients.
Dosage form: Each tablet contains 10 mg sumatriptan and 60 mg naproxen.
Dose: For pediatrics, take a 10/60 mg tablet once but do not exceed one 85/500 mg tablet.

Tiotropium Bromide; Olodaterol (Stiolto Respimat, Boehringer Ingelheim)
Pharmacology: Combination consisting of an anticholinergic agent and a long acting beta adrenergic agonist.
Indication: Maintenance therapy for COPD.
Dosage form: Oral inhalation spray containing 3.124 mcg tiotropium bromide monohydrate and 2.736 mcg olodaterol HCl per actuation.
Dose: Take two actuations by mouth once daily. Doses should be at the same time every day.

NEW DRUG INDICATIONS

Moxifloxacin (Avelox, Bayer HealthCare Pharmaceuticals)
Pharmacology: Fluoroquinolone antibiotic.
New Indication: Treatment of pneumonic or septicemic plague caused by susceptible isolates of *Yersinia pestis*.
Dose: 400 mg by mouth or intravenously every day for 10-14 days.

Rifaximin (Xifaxan, Salix Pharmaceuticals)
Pharmacology: Rifamycin antibiotic.
New Indication: Irritable bowel syndrome with diarrhea.
Dose: Take a single 550 mg tablet three times a day for 14 days.

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