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

Moxifloxacin (Moxifloxacin, Fresenius Kabi USA)
Pharmacology: Fluoroquinolone antibiotic.
Indication: Indicated for acute bacterial sinusitis; acute bacterial exacerbation and chronic bronchitis; community acquired pneumonia; skin and skin structure infections; and complicated intra-abdominal infections.
Adverse Drug Reactions: Nausea, diarrhea, headache, and dizziness.
Dose: 400 mg every 24 hours for 7-21 days, depending on indication.
Formulation: Injection.
Warnings/Contraindications: Prolongation of QT interval, hypersensitivity reactions, CNS events (e.g., dizziness, confusion, hallucination, etc); *Clostridium difficile*-associated diarrhea; peripheral neuropathy; high sodium load.
Notes: Moxifloxacin may interact with warfarin, class IA and class III antiarrhythmics, and antidiabetic agents.

Ivabradine (Corlanor, Amgen)
Pharmacology: Hyperpolarization-activated cyclic nucleotide-gated channel blocker.
Indication: Reduce the risk of hospitalization for worsening heart failure in patients with stable, symptomatic chronic heart failure with a left ventricular ejection fraction ≤ 35% who are in sinus rhythm. Resting heart rate should be ≥ 70 beats per minutes and either are on maximum tolerated doses of beta-blockers or have a contraindication to beta-blockers.
Adverse Drug Reactions: Bradycardia, hypertension, atrial fibrillation, and luminous phenomena (phosphenes).
Dose: The starting dose is 5 mg twice daily. The dose can be adjusted after 2 weeks based on heart rate. The maximum dose is 7.5 mg twice daily.
Formulation: 5-mg, and 7.5-mg tablets.
Warnings/Contraindications: Contraindications include: acute decompensated heart failure; blood pressure <90/50 mmHg; sick sinus syndrome; resting heart rate < 60bpm prior to treatment; severe hepatic impairment; and pacemaker dependence.
Notes: Significant interactions with CYP3A4 inhibitors (increases ivabradine plasma concentrations); CPY3A4 induces (decrease ivabradine plasma concentrations); negative chronotropes; and pacemakers.

Methylphenidate HCl (Aptensio XR, Rhodes Pharms)
Pharmacology: Central nervous system stimulant.
Indication: Attention deficit hyperactivity disorder (ADHD).
Adverse Drug Reactions: abdominal pain, decreased appetite, headache, and insomnia.
Dose: The dosage for patients ≥ 6 years: 10 mg once daily with or without food in the morning. The dosage may be increased weekly in 10 mg increments. Daily doses > 60 mg is not recommended.
Formulation: Extended-release capsules: 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 50 mg, and 60 mg.
Warnings/Contraindications: Contraindications: Concurrent treatment with monoamine oxidase inhibitor (MAOI) or use with a MAOI within the past 14 days. Warnings include serious cardiovascular events; blood pressure/heart rate increases; psychiatric adverse reactions; priapism; peripheral vasculopathy; and long-term suppression of growth.
Notes: Capsules may be swallowed whole or opened and sprinkled onto applesauce.

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Deoxycholic Acid (Kybella, Kythera Biopharma Inc.)

Pharmacology: Cytolytic.

Indication: Improve the appearance of moderate to severe convexity or fullness associated with submental (chin) fat in adults.

Adverse Drug Reactions: Injection site edema/swelling, hematoma, pain, numbness, erythema, and induration.

Dose: 0.2 mL injections paced 1 cm apart until all sites in the planned treatment area have been injected. Up to 50 injections or 10 mL may be injected in a single treatment. Up to 6 single treatments may be administered at intervals no less than 1-month apart.

Formulation: 20 mg / 2 mL single use vials.

Warnings/Contraindications: Marginal mandibular nerve injury, dysphagia, and submental hemotoma/bruising.

Notes: Do not mix with other agents or dilute. This product is contraindicated in the presence of infection at the injection site.

Meropenem for Injection USP and Sodium Chloride Injection (Meropenem; Sodium Chloride, B Braun)

Pharmacology: Carbapenem antibacterial agent.

Indication: Treatment of complicated skin and skin structure infections; complicated intra-abdominal infections and bacterial meningitis.

Adverse Drug Reactions:

Dose: Dependent upon indications (500 mg – 1000 mg every 8 hours).

Formulation: 500 mg and 1000 mg solution for injection.

Warnings/Contraindications: Seizures, CNS adverse effects, *Clostridium difficile*-associated diarrhea, and thrombocytopenia.

Notes: Dose must be adjusted based on degree of renal impairment.

Codeine Polisirex; Chlorpheniramine Polisitirex (Tuzistra XR, Tris Pharma, Inc.)

Pharmacology: Narcotic antitussive and analgesic; H1 receptor antagonist.

Indication: Relief of cough and symptoms associated with upper respiratory allergies or a common cold.

Adverse Drug Reactions: Nausea, vomiting, constipation, abdominal distension, abdominal pain, blurred vision, etc.

Dose: 10 mL every 12 hours. Do not exceed 2 doses (20 mL) in 24 hours.

Formulation: Extended-release oral suspension: codeine 14.7 mg; chlorpheniramine-2.8 mg / 5 mL.

Warnings/Contraindications: Contraindications-postoperative pain management of children post tonsillectomy and/or adenoidectomy. Warnings-risk of death in patients who are ultra-rapid metabolizers of codeine; dose-related respiratory depression; and drug dependence.

Notes: Potential drug-drug interactions include opioids, antihistamines, antipsychotics, anti-anxiety agents or other CNS depressants; MAOIs or tricyclic antidepressants; anticholinergic drugs; inhibitors or inducers of CYP450 2D6/3A4.

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New drug approvals, formulations, and indications. *New Drug Fax Sheet.* 2015 May 18;20(13):1-2.