CENTER FOR HEALTHCARE INNOVATION AND PATIENT OUTCOMES RESEARCH

Samford University
McWhorter School of Pharmacy

NEW DRUG FAX SHEET

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

Volume 22 (Issue 7) **July 17, 2017**

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

Delafloxacin (Baxdela, Melinta Therapeutics, Inc.)

Pharmacology: Flouroquinolone antibacterial.
Indication: Treatment of acute bacterial skin and skin structure infections (ABSSSI) caused by susceptible bacteria.
Adverse Drug Reactions: Nausea, diarrhea, headache, transaminase elevations and vomiting.
Dose: For injection - 300 mg infused over 60 minutes, every 12 hours or 450-mg tablet orally every 12 hours for 5-14 days.
Formulation: For injection - 300 mg (equivalent to 433 mg delafloxacin meglumine); oral tablets: 450 mg (equivalent to 649 mg delafloxacin meglumine).
Warnings/Contraindications: Hypersensitivity reactions, *Clostridium difficile*-associated diarrhea.
Notes: Renal dosage may be necessary in patients receiving the intravenous dose of delafloxacin with an eGFR between 15-29 mL/min/1.73m^2).

Betrixaban (Bevyxxa, Portola Pharma Inc.)

Pharmacology: Factox Xa inhibitor.
Indication: Prophylaxis of venous thromboembolism (VTE) in adult patients hospitalized for an acute medical illness who may be susceptible to VTE.
Adverse Drug Reactions: Bleeding.
Dose: Initial single dose is 160 mg, followed by 80 mg once daily taken with food for 35-42 days.
Formulation: 40- and 80- mg capsules.
Warnings/Contraindications: Risk of bleeding, severe renal impairment, concomitant P-gp inhibitors.
Notes: The dose of betrixaban needs to be reduced in patients with renal impairment and those receiving P-gp inhibitors.

Hyaluronidase; Rituximab (Rituxan Hycela, Genetech Inc.)

Pharmacology: Combination of rituximab, CD20-directed cytolytic antibody and hyaluronidase human, an endoglycosidase.
Indication: Monotherapy for relapsed or refractory, follicular lymphoma (FL); previously untreated FL in combination with other chemotherapy; non-progressive FL as a single agent; diffuse large B-cell lymphoma (DLBCL); and chronic lymphocytic leukemia (CLL).
Adverse Drug Reactions: FL: infections, neutropenia, nausea, constipation, cough, and fatigue; DLBCL: infections, neutropenia, alopecia, nausea, and anemia; and CLL: infections; neutropenia; nausea; thrombocytopenia; pyrexia; vomiting; and injection site erythema.
Dose: FL/DLBCL: 1400 mg/ 23,400 Units (1,400 mg rituximab and 23,400 Units hyaluroidase human) subcutaneously according to the recommended schedule. CLL: Administer 1,600 mg/26,800 Units (1,600 mg rituximab and 26,800 Units hyaluronidase human) subcutaneously according to the recommended schedule.
Formulation: 1,400 mg rituximab and 23,400 Units hyaluronidase human per 11.7 mL (120 mg/2,000 Units per mL); 1,600 mg rituximab and 26,800 Units hyaluronidase human per 13.4 mL (120 mg/2,000 Units per mL).
Warnings/Contraindications: Tumor lysis syndrome; infections; cardiac adverse reactions; renal toxicity; bowel obstrucdtion/preformation; live immunizations; and embryo-fetal toxicity.
Notes: All doses should be premediated with acetaminophen and antihistamine before use. Consider premedication with glucocorticoids.

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NEW DRUG FORMULATIONS

Aminolevulinic Acid Hydrochloride (Gleolan, NX Development)
Pharmacology: Optical imaging agent.
Indication: Glioma.
Dosage form: Oral solution: 1,500 mg ALA HCl lypholized powder, equivalent to 1,170 mg ALA per via. The reconstituted solution contains 30 mg/mL.
Dose: Oral dose: 20 mg/kg.

Ritonavir (Norvir, Abbvie, Inc.)
Pharmacology: Protease inhibitor.
Indication: Oral powder is indicated for pediatric patients with HIV-1 infection.
Dosage form: Tablet: 100 mg; oral solution: 80 mg/mL; oral powder: 100 mg per packet.
Dose: Adults: 600 mg twice daily with meals; children twice daily for children > 1 month of age based on body surface area, do not exceed 600 mg twice daily with meals.

Methylphenidate (Cotempla XR-ODT, Neos Therap, Inc.)
Pharmacology: Central Nervous System (CNS) stimulant.
Indication: Treatment of Attention Deficit Hyperactivity Disorder (ADHD) in pediatric patients 6 to 17 years of age.
Dosage form: Extended-release orally disintegrating tablets: 8.6 mg, 17.3 mg, and 25.9 mg.
Dose: Pediatric patients aged 6-17 years: 17.3 mg given orally once daily in the morning. Do not exceed 51.8 mg.

Mixed salts of a single-entity amphetamine (Mydayis, Shire Dev, LLC)
Pharmacology: CNS stimulant.
Indication: ADHD in patients 13 years and older.
Dosage form: Extended-release capsules: 12.5 mg, 25 mg, 37.5 mg, and 50 mg.
Dose: The recommended starting dose for adults and pediatric patients aged 13-17 years is 12.5 mg. The maximum dose for adults is 50 mg and 25 mg for pediatric patients.