

NEW DRUG FAX SHEET



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

Volume 22 (Issue 1)

January 16, 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

Nusinersen (Spinraza, Biogen)

Pharmacology: Antisense oligonucleotide.

Indication: Treatment of spinal muscular atrophy (SMA) in pediatric and adult patients.

Adverse Drug Reactions: Lower respiratory infection, upper respiratory infection, and constipation.

Dose: 2.4mg/ml Intratecal injection

Formulation: Available as 12mg/5mL (2.4mg/mL) solution for injection in a single dose vial.

Warnings/Contraindications: Thrombocytopenia, coagulation abnormalities, and renal toxicity.

Notes: conduct platelet count, prothrombin time, activated partial thromboplastin time, quantitative spot urine protein testing at baseline and prior to each dose and as clinically needed

Rucaparib (Rubraca, Clovis Oncology Inc.)

Pharmacology: Poly (ADP-ribose) polymerase (PARP) Inhibitor.

Indication: Monotherapy for the treatment of patients with deleterious BRCA mutation (germline and/or somatic) associated advanced ovarian cancer who have been treated with two or more chemotherapies.

Adverse Drug Reactions: Nausea, fatigue, vomiting, anemia, abdominal pain, dysgeusia, constipation, decreased appetite, diarrhea, thrombocytopenia, dyspnea, and abnormal laboratory values.

Dose: 200mg and 300mg oral tablet

Formulation: 200mg and 300mg oral Tablet.

Warnings/Contraindications: Myelodysplastic syndrome/Acute myeloid leukemia (MDS/AML) and embryo-fetal toxicity

Notes: Monitor patients for hematological toxicity at baseline and monthly thereafter

NEW DRUG FORMULATIONS

Tigecycline (Tygacil, Fresenius Kabi)

Pharmacology: Tetracycline.

Indication: Complicated skin and skin structure infections, complicated intra-abdominal infections, and community-acquired bacterial pneumonia.

Dosage form: 50mg, lyophilized powder for reconstitution in a single dose 10mL vial.

Dose: 10ml/50mg

Atropine Sulfate (Isopto Atropine, Alcon Pharms LTD)

Pharmacology: Muscarinic antagonist.

Indication: Mydriasis, cycloplegia, and penalization of the healthy eye in the treatment of amblyopia.

Dosage form: 10mg/mL ophthalmic solution.

Dose: 10mg/ml

NEW DRUG FORMULATIONS (CONTINUED)

Empagliflozin and Metformin Hydrochloride Extended Release (Synjardy, Boehringer Ingelheim)

Pharmacology: Combination of a sodium-glucose co-transporter 2 (SGLT2) inhibitor and a biguanide.

Indication: An adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus

Dosage form: Oral tablets, available as: 10 mg empagliflozin/1000 mg metformin hydrochloride extended-release
12.5 mg empagliflozin/1000 mg metformin hydrochloride extended-release; 25 mg empagliflozin/1000 mg metformin hydrochloride extended-release

Dose: 25mg/2000mg

Sodium Sulfate, Potassium Sulfate, Magnesium Sulfate (Colprep Kit, Gator Pharma Inc.)

Pharmacology: Osmotic laxative.

Indication: Cleansing of the colon as a preparation for colonoscopy in adults .

Dosage form: Oral solution; Two bottles per ColPrep Kit. Each bottle contains sodium sulfate 17.5 g, potassium sulfate 3.13 g, and magnesium sulfate 1.6 g.

Dose: 17.5g/3.13g/1.6g

Levothyroxine Sodium (Tirosint-Sol, IBSA Institute Biochimique SA)

Pharmacology: L-thyroxine (T4).

Indication: Hypothyroidism and Pituitary Thyrotropin (thyroid-stimulating hormone, TSH) Suppression.

Dosage form: Oral Solution containing L-thyroxine at the following concentrations: 13, 25, 50, 75, 88, 100, 112, 125, 137, 150, 175, 200 mcg/mL

Dose: 1.6mcg/kg/day

Caspofungin Acetate (Cancidas, Fresenius Kabi)

Pharmacology: Echinocandin antifungal.

Indication: Empirical therapy for presumed fungal infections in febrile, neutropenic patients; candidemia and the following Candida infections: intra-abdominal abscesses, peritonitis and pleural space infections; esophageal candidiasis; invasive aspergillosis in patients who are refractory to or intolerant of other therapies.

Dosage form: 50 or 70 mg lyophilized powder (plus allowance for overfill) in a single dose vial for reconstitution for injection.

Dose: 5mg/ml or 7mg/ml

NEW DRUG INDICATIONS

Bevacizumab (Avastin, Genentech)

Pharmacology: Recombinant humanized monoclonal IgG1 antibody.

New Indication: Recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer that is: platinum-resistant in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan, or platinum-sensitive in combination with carboplatin and paclitaxel or in combination with carboplatin and gemcitabine, followed by Avastin as a single agent.

Dose: Platinum-resistant recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer: 10 mg/kg IV every 2 weeks with paclitaxel, pegylated liposomal doxorubicin or weekly topotecan or 15 mg/kg IV every 3 weeks with topotecan given every 3 weeks. Platinum-sensitive recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer: 15 mg/kg IV every 3 weeks in combination with carboplatin/paclitaxel for 6-8 cycles, followed by 15 mg/kg IV every 3 weeks as a single agent or 15 mg/kg IV every 3 weeks in combination with carboplatin/gemcitabine for 6-10 cycles, followed by 15 mg/kg IV every 3 weeks as a single agent.