

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.

NEW DRUG APPROVALS

Aspirin/Omeprazole (Yosprala, Aralez Pharms Inc)

Pharmacology: Antiplatelet/Proton Pump Inhibitor combination (PPI).

Indication: Approved for patients at risk of developing aspirin induced gastric ulcers.

Adverse Drug Reactions: Gastritis, non-cardiac chest pain, nausea, diarrhea, gastric polyps.

Dose: 81mg/40mg, 325mg/40mg.

Formulation: 81 mg delayed-release aspirin/40 mg immediate-release omeprazole, 325 mg delayed-release aspirin/40 mg immediate-release omeprazole.

Warnings/Contraindications: Coagulation abnormalities, gastrointestinal disturbances such as bleeding or ulcers, should not be used in renal failure or if patient has any type of hepatic impairment, and PPI use is associated with increases risk of *Clostridium Difficile* infections.

Notes: Aspirin/Omeprazole is contraindicated in children with suspected viral infections, due to risk of Reyes syndrome. Avoid aspirin/omeprazole in pregnant women >30 weeks of gestation. Avoid abrupt discontinuation, as it increases risk of heart attack and stroke.

Eteplirsen (Exondys 51, Sarepta Therapeutics Inc)

Pharmacology: Antisense oligonucleotide that selectively binds to exon 51 of the dystrophin pre-messenger ribonucleic acid (pre-mRNA).

Indication: Duchenne Muscular Dystrophy (DMD) with DMD gene that has confirmed exon 51 skipping.

Adverse Drug Reactions: Contact dermatitis, vertigo, vomiting.

Dose: 30mg/kg once weekly.

Formulation: 100 mg/2 mL (50 mg/mL) in single-dose vial, 500 mg/10 mL (50 mg/mL) in single-dose vial.

Warnings/Contraindications: None listed in the package insert.

Notes: Should be administered as an IV infusion over 35 to 60 minutes. Dilution is required prior to administration.

Canagliflozin;Metformin (Invokamet XR, Janssen Pharms)

Pharmacology: Sodium-glucose co-transporter 2 (SGLT2) inhibitor/ biguanide combination product.

Indication: Approved for treatment of Type II Diabetes in which metformin and canagliflozin are both appropriate.

Adverse Drug Reactions: Adverse events associated with canagliflozin are female genital mycotic infections, urinary tract infections, and increased urination. Adverse reactions associated with metformin are diarrhea, nausea, vomiting, flatulence, asthenia, indigestion, abdominal discomfort, and headache.

Dose: 50/500, 50/500mg, 50mg /1000mg, 150mg/1000mg extended-release tablets

Formulation: Canagliflozin 50 mg/metformin Hcl 500 mg extended-release, canagliflozin 50 mg/metformin Hcl 1,000 mg extended-release, canagliflozin 150mg/metformin Hcl 500 mg extended-release, canagliflozin 150 mg/metformin Hcl 1,000 mg extended-release

Warnings/Contraindications: Metabolic acidosis, diabetic ketoacidosis, may cause genital tract infections, hypotension, increased risk of bone fractures, and hypersensitivity reactions.

Notes: Monitor renal function, drug-drug interactions with carbonic anhydrase inhibitors (increased risk of lactic acidosis). Monitor use with drugs that are tubular secreted (cimetidine). Limit alcohol intake. Advise against use in pregnancy in second and third trimester.

Rubidium RB- 82 Chloride (Ruby-Fill, CardioGen-82, Jubilant Draximage)

Pharmacology: Radiopharmaceutical.

Indication: Rest and stress myocardial perfusion imaging.

Adverse Drug Reactions: U.S. Black Box warning of unintended radiation exposure can occur if drug limits are exceeded.

Dose: Myocardial perfusion imaging: IV: Rest or stress imaging: 40 mCi as a single dose; maximum single dose: 60 mCi.

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Rubidium RB- 82 Chloride (Ruby-Fill, CardioGen-82, Jubilant Draximage) (continued)

Formulation: 30mCi single dose, 40mCi single dose, 60mCi single dose.

Warnings/Contraindications: Increases risk of cardiovascular events (arrhythmias, heart attack, hypotension), malignancies.

Notes: Increases risk of fluid overload in the elderly and in heart failure patients. Use appropriate measures when using radiopharmaceuticals and use under supervision of experienced personnel.

NEW DRUG FORMULATIONS

Levonorgestrel (Kyleena, Bayer Healthcare Pharms)

Pharmacology: Synthetic progestin.

Indication: Approved for the prevention of pregnancy for up to 5 years and treatment of menorrhagia.

Dosage form: Progestin containing intrauterine T-shaped system with a steroid reservoir containing 19.5 mg levonorgestrel.

Dose: IUD delivers 20 mcg/day of levonorgestrel, 19.5mg levonorgestrel total in system.

Enalapril Maleate (Epaned, Silvergate Pharms)

Pharmacology: Angiotensin-converting enzyme (ACE) inhibitor.

Indication: Treatment of hypertension, symptomatic heart failure, and symptomatic left ventricular malfunction.

Dosage form: 1mg/mL enalapril maleate oral solution.

Dose: Hypertension: recommended initial dose is 5 mg once daily. Maximum dose is 40 mg daily.

Heart Failure: Start at 2.5 mg twice daily. May titrate up to 20 mg twice daily if drug is tolerated. Symptomatic left ventricular malfunction: Starting dose of 2.5 mg twice daily. May titrate up to 10 mg twice daily.

Adalimumab (Amjevita, Amgen Inc)

Pharmacology: Adalimumab is a monoclonal antibody specific for tumor necrosis factor-alpha (TNF-alpha). Biosimilar of adalimumab (Humira).

Indication: Treatment of moderate-severe rheumatoid arthritis, moderate-severe juvenile idiopathic arthritis, ankylosing spondylitis, moderate-severe plaque psoriasis, reducing signs and symptoms of moderate-severe Crohn's disease and ulcerative colitis.

Dosage form: SureClick autoinjector single-use prefilled syringe: 40 mg/0.8 ml. Prefilled glass syringe: 40 mg/0.8 ml or 20 mg/0.4 ml.

Dose: Rheumatoid Arthritis, Psoriatic Arthritis, or Ankylosing Spondylitis: 40 mg every other week.

Juvenile Idiopathic Arthritis: 15 kg-30 kg use 20 mg every other week, if ≥ 30 kg use 40 mg every other week.

Adult Crohn's Disease and Ulcerative Colitis Initial dose on day 1: Either 160 mg (four 40 mg injections in one day or two 40 mg injections per day for two consecutive days). The second dose of 80mg is two weeks later on day 15. The third dose is two weeks later on day 29 and begins maintenance therapy of 40 mg every other week.

Plaque Psoriasis: 80 mg initial dose, followed by 40 mg every other week starting one week after receiving initial dose.

Ustekinumab (Stelara, Janssen Biotech)

Pharmacology: Human interleukin-12 and Human interleukin-23 antagonist

Indication: Moderate-severe plaque psoriasis, active psoriatic arthritis, moderate-severe active Crohn's disease

Dosage form: IV Infusion: 130 mg/26 mL (5 mg/mL) solution in a single-dose vial.

Dose: Psoriasis Adult Dosage: ≤ 100 kg then 45kg subcutaneously initially and four weeks later, with maintenance doses of 45mg every 12 weeks. If ≥ 100 kg then 90mg initially and four weeks later, followed by maintenance doses of 90mg every 12 weeks. Psoriatic Arthritis Adult Dosage: Recommended dosage of 45mg subcutaneously initially and four weeks later. In patients with both psoriatic arthritis and moderate-severe plaque psoriasis weighing ≥ 100 kg, recommended dose is 90mg initially and four weeks later. Crohn's Disease Recommended adult weight based dosing: if ≤ 55 kg dose= 260mg (2 vials), ≥ 55 kg-85kg dose=390mg (3 vials), and if ≥ 85 kg dose= 520mg (4 vials).

Levoleucovorin Calcium (Levoleucovorin, Actavis LLC)

Pharmacology: Folate analog

Indication: Rescue after high-dose methotrexate therapy in osteosarcoma. Decreasing the toxicity of folate antagonist, overdose, or reduced methotrexate elimination.

Dosage form: 175 mg lyophilized powder in single-dose vial for reconstitution.

Dose: For rescue after high-dose methotrexate therapy or methotrexate overdose: start rescue at 7.5 mg every 6 hours, 24 hours after receiving Methotrexate therapy, continue until methotrexate level is below 5×10^{-8} M (0.05 micromolar). In case of methotrexate overdose begin therapy as soon as possible.