

NEW DRUG FAX SHEET



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Volume 23 (Issue 3)

March 19, 2018

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

Bictegravir; emtricitabine; tenofovir alafenamide (Biktarvy, Gilead Science, Inc)

Pharmacology: HIV integrase strand transfer inhibitor (INSTI) and HIV-1 nucleoside analog reverse transcriptase inhibitor (NRTI).

Indication: Treatment of HIV-1 infection in adults with no antiretroviral treatment history or to replace the current antiretroviral regimen in those who are virologically suppressed.

Adverse Drug Reactions: Diarrhea, nausea, and headache.

Dose: One tablet taken with or without food.

Formulation: 50 mg of bictegravir (equivalent to 52.5 mg of bictegravir sodium), 200 mg of emtricitabine, and 25 mg of tenofovir alafenamide (equivalent to 28mg of tenofovir alafenamide fumarate).

Warnings/Contraindications: Immune reconstitution syndrome; new onset or worsening renal impairment; lactic acidosis/severe hepatomegaly with steatosis.

Notes: Coadministration with other antiretroviral medications is not recommended.

Tezacaftor; Ivacaftor (Symdeko, Vertex Pharms)

Pharmacology: Cystic fibrosis transmembrane conductance regulator.

Indication: Treatment of patients with cystic fibrosis (aged 12 years and older) who are homozygous for the *F508del* mutation or who have at least one mutation in the cystic fibrosis transmembrane conductance regulator (*CFTR*) gene.

Adverse Drug Reactions: Headache, nausea, sinus congestion, and dizziness.

Dose: One tablet in the morning and evening (12 hours apart) with a fat-containing food.

Formulation: Tezacaftor 100 mg/ivacaftor 150 mg fixed dose combination tablets and ivacaftor 150 mg tablets.

Warnings/Contraindications: Elevated transaminases; use caution with use of CYP3A inducers; cataracts.

Notes: Reduce dose in patients with moderate and severe hepatic impairment.

Apalutamide (Erleada, Janssen Biotech)

Pharmacology: Androgen receptor inhibitor.

Indication: Treatment of patients with non-metastatic castration-resistant prostate cancer.

Adverse Drug Reactions: Fatigue, hypertension, rash, diarrhea, nausea, weight decreased, arthralgia, fall, hot flush, decreased appetite, fracture, and peripheral edema.

Dose: Four 60-mg tablets administered orally once daily.

Formulation: 60-mg tablets.

Warnings/Contraindications: Falls and fractures; seizures.

Notes: Swallow tablets whole. Concomitant administration with medications that are sensitive substrates of CYP3A4, CYP2C19, CYP2C9, UGT, P-gp, BCRP, or OATP1B1 may result in loss of activity of these medications.

NEW DRUG FORMULATIONS

Sodium Pertechnetate (Radiogenix System, Northstar Medical Radioisotopes, LLC)

Pharmacology: Technetium Tc-99m generator.

Indication: Salivary gland imaging and nasolacrimal drainage system imaging; thyroid imaging and vesicoureteral imaging.

Dosage form: Clear, colorless solution containing 30 mCi/mL to 1153 mCi/ML of technetium Tc-99m radioactivity in approximately 5 mL volume.

Dose: Dosage range depends on indication.

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NEW DRUG FORMULATIONS (CONTINUED)

Dexamethasone (Dexycu, Icon Bioscience, Inc)

Pharmacology: Corticosteroid.

Indication: Postoperative inflammation.

Dosage form: Intraocular suspension; 9% equivalent to dexamethasone 103.4 mg/mL in a single-dose vial provided in a kit.

Dose: 0.005 mL of dexamethasone into the posterior chamber inferiorly behind the iris at the end of ocular surgery.

Benzhydrocodone; acetaminophen (Apadaz, Kempharm Inc)

Pharmacology: Opioid / acetaminophen combination.

Indication: Short-term management (no more than 14 days) management of acute pain, severe enough to require an opioid analgesic for which alternative treatments are inadequate.

Dosage form: Immediate release tablets: 6/12 mg benzhydrocodone (equivalent to 6.67 mg benzhydrocodone hydrochloride) and 325 mg acetaminophen.

Dose: Initiate treatment as 1-2 tablets every 4-5 hours as needed for pain. Do not exceed 12 tablets in a 24-hour period.

Lamivudine; tenofovir disoproxil fumarate (Cimduo, Matrix Labs)

Pharmacology: Nucleoside reverse transcriptase inhibitors.

Indication: Treatment of HIV-1 infection in adult and pediatric patients weighing at least 35 kg.

Dosage form: Tablets: 300 mg lamivudine and 300 mg tenofovir disoproxil fumarate (equivalent to 245 mg of tenofovir disoproxil).

Dose: One tablet taken orally once daily with or without food.

Lidocaine (Ztlido, Scilex Pharma)

Pharmacology: Amide local anesthetic.

Indication: Relief of pain associated with post-herpetic neuralgia.

Dosage form: Single use topical system, 1.8% lidocaine.

Dose: Apply up to 3 topical systems once for up to 12 hours in a 24-hour period.

Efavirenz; lamivudine; tenofovir disoproxil fumarate (Symfi Lo, Mylan Pharms Inc)

Pharmacology: Non-nucleoside reverse transcriptase inhibitor, nucleoside reverse transcriptase inhibitor.

Indication: Complete regimen for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adult and pediatric patients weighing at least 35 kg.

Dosage form: Tablet: 400 mg efavirenz, 300 mg lamivudine and 300 mg tenofovir disoproxil fumarate (equivalent to 245 mg of tenofovir disoproxil).

Dose: One tablet taken orally once daily on an empty stomach, preferably at bedtime.

Amantadine (Osmolex ER, Osmotica Pharm US)

Pharmacology: Weak uncompetitive antagonist of the NMDA receptor.

Indication: Treatment of Parkinson's disease and drug-induced extrapyramidal reactions in adult patients.

Dosage form: Extended-release tablets containing 129 mg, 193 mg, or 258 mg amantadine.

Dose: The initial dose is 129 mg orally once daily in the morning; dose can increase to 322 mg once daily.

Ibrutinib (Imbruvica; Pharmacyclics, LLC)

Pharmacology: Kinase inhibitor.

Indication: Mantle cell lymphoma; chronic lymphocytic leukemia; chronic lymphocytic leukemia; Waldenstrom's macroglobulinemia; marginal zone lymphoma; and chronic graft vs. host disease.

Dosage form: Capsules-70 mg, 140 mg; tablets-140 mg, 280 mg, 420 mg, and 560 mg.

Dose: Varies by indication.

NEW DRUG INDICATIONS

Abemaciclib (Verzenio, Eli Lilly and Co)

Pharmacology: Selective ATP-competitive inhibitor of cyclin dependent kinases (CDK) 4 and 6.

New Indication: Initial treatment for advanced breast cancer.

Dose: 150 mg twice daily.

Luliconazole (Luzu, Ortho Dermatologics)

Pharmacology: Azole antifungal.

New Indication: Pediatric patients with athlete's foot, jock itch, and ringworm.

Dose: Apply to the affected area topically once daily for 7 days.

Durvalumab (Imfinzi, AstraZeneca)

Pharmacology: anti-PD-L1 (programmed death ligand-1) human monoclonal antibody.

New Indication: Unresectable stage III non-small cell lung cancer.

Dose: 10 mg/kg every 2 weeks.

Hydroxyprogesterone caproate (Makena, AMAG Pharmaceuticals)

Pharmacology: Progesterone.

New Indication: Reduce the risk of preterm birth in certain at-risk women.

Dose: 250 mg (1 mL) once weekly (every 7 days).

Abiraterone (Zytiga, Janssen Pharmaceuticals)

Pharmacology: CYP 17 inhibitor.

New Indication: Metastatic prostate cancer.

Dose: 1000 mg once daily in combination with prednisone.

Ferumoxytol (Feraheme, AMAG Pharmaceuticals)

Pharmacology: Iron replacement therapy.

New Indication: Adult patients with iron deficiency anemia.

Dose: 510 mg followed by a second 510 mg dose 3-8 days later.

Avibactam and ceftazidime (Avycaz, Allergan)

Pharmacology: Non- β lactam β -lactamase inhibitor and third-generation, antipseudomonal cephalosporin.

New Indication: Treatment of hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia.

Dose: 2.5 g IV every 8 hours.