

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

Trastuzumab-DTTB (Ontruzant, Samsung Bioepis Co, LTD)

Pharmacology: HER2/neu receptor antagonist.

Indication: Treatment of HER2-overexpressing breast cancer and gastric or gastroesophageal junction adenocarcinoma.

Adverse Drug Reactions: Headache, diarrhea, nausea, chills, congestive heart failure, insomnia, cough, rash, neutropenia, upper respiratory tract infections, fever, fatigue, anemia, weight loss, mucosal inflammation, nasopharyngitis, and dysgeusia.

Dose: Dosage varies based on indication. The starting dose is 4-8 mg/kg as a 90-minute infusion.

Formulation: 150 mg lyophilized powder for reconstitution.

Warnings/Contraindications: Exacerbation of chemotherapy-induced neutropenia.

Notes: This drug cannot be substituted for or with ado-trastuzumab emtansine.

NEW DRUG FORMULATIONS

Sumatriptan (Tosymra, Dr. Reddy's Labs, LTD)

Pharmacology: 5-HT_{1B/1D} receptor agonist.

Indication: Acute treatment of migraine with or without aura in adults.

Dosage form: Nasal spray, 10 mg.

Dose: Single dose of 10 mg of nasal spray.

Amphetamine (Evekeo ODT, Arbor Pharms, LLC)

Pharmacology: CNS stimulant.

Indication: Treatment of attention deficit hyperactivity disorder (ADHD).

Dosage form: Orally disintegrating tablets- 5 mg, 10 mg, 15 mg, and 20 mg.

Dose: Starting dose is 5 mg once or twice daily.

Colchicine (Gloperba, Romeg Therapeutics, LLC)

Pharmacology: Antigout agent.

Indication: Prophylaxis of gout flares in adults.

Dosage form: 0.6 mg/5 mL oral solution.

Dose: 0.6 mg (5 mL) once or twice daily. Maximum dose is 1.2 mg/day.

NEW DRUG INDICATIONS

Acetaminophen and benzhydrocodone (Apadaz, KemPharm)

Pharmacology: Combination non-opioid / opioid analgesic.

New Indication: Short term use for pain.

Dose: New dosage strength of benzhydrocodone 4.08 mg / APA 325 mg, and benzhydrocodone 8.16 mg / APAP 325 mg.

Cabozantinib (Cabometyx, Exelixis)

Pharmacology: Tyrosine kinase inhibitor.

New Indication: Treatment of advanced renal cell carcinoma and hepatocellular carcinoma who have been treated with sorafenib.

Dose: 60 mg once daily without food.

Tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccine adsorbed (Tdap, Sanofi)

Pharmacology: Vaccine.

New Indication: Active booster immunization for the prevention of tetanus, diphtheria and pertussis.

Dose: 0.5 mL per dose.

Influenza virus vaccine, inactivated (Fluzone Quadrivalent, Sanofi)

Pharmacology: Vaccine.

New Indication: Active immunization against influenza disease caused by influenza virus subtypes A and type B contained in the vaccine.

Dose: 0.5 mL in children as young as 6 months of age.

Ospemifene (Osphena, Duchesnay USA, Inc.)

Pharmacology: Estrogen agonist/antagonist.

New Indication: Treatment of symptoms of vulvar and vaginal atrophy due to menopause, including severe dyspareunia and moderate to severe vaginal dryness.

Dose: One, 60-mg tablet once daily.

Ibrutinib (Imbruvica, Janssen)

Pharmacology: Bruton's tyrosine kinase inhibitor.

New Indication: First non-chemotherapy combination regimen for treatment-naïve patients with chronic lymphocytic leukemia (CLL).

Dose: Dose of CLL is 420 mg taken orally once daily.

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