

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

Barium sulfate (E-Z-HD, Bracco Diagnostic Inc.)

Pharmacology: Radiographic contrast agent.

Indication: Barium sulfate is used in double contrast radiographic esophagus, stomach and duodenum examinations in patients 12 years and older.

Adverse Drug Reactions: Nausea, vomiting, diarrhea and abdominal cramping are common.

Dose: Oral dose for adults and pediatric patients 12 years and older is between 65 mL to 135 mL (155 to 321 grams)

Formulation: Oral Suspension or Smoothie: 340 grams (98%), fine white powder, single dose in HDPE plastic bottle for reconstitution.

Warnings/Contraindications: Patient should maintain adequate hydration in days prior to receiving barium sulfate to avoid obstruction or impaction caused by baroliths (inspissated barium associated with feces). Perforation of the gastrointestinal (GI) tract, obstruction of the GI tract, conditions associated with high risk of aspiration or high risk of GI perforation and any known hypersensitivity to barium sulfate.

Notes: Pregnancy: maternal use is not expected to result in fetal exposure to the drug.

Barium sulfate (READI-CAT 2, Bracco Diagnostic Inc.)

Pharmacology: Radiographic contrast agent.

Indication: Radiographic contrast agent, for use in computed tomography of the abdomen to delineate the gastrointestinal tract in adult and pediatric patients.

Adverse Drug Reactions: Nausea, vomiting, diarrhea and abdominal cramping are common.

Dose: Adults and pediatric patients 12 years and older: 450mL to 900mL (9g to 18g of barium sulfate, respectively). Patients younger than 12 years of age: adjust dose based on relative GI volume.

Formulation: Oral powder for reconstitution as a paste, suspension, cream or capsule; is also formulated for rectal suspension.

Warnings/Contraindications: Patient should maintain adequate hydration in days prior to receiving barium sulfate to avoid obstruction or impaction caused by baroliths. Perforation of the gastrointestinal (GI) tract, obstruction of the GI tract, conditions associated with high risk of aspiration or high risk of GI perforation and any known hypersensitivity to barium sulfate.

Notes: Pregnancy: maternal use is not expected to result in fetal exposure to the drug.

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NEW DRUG FORMULATIONS

Sumatriptan (Onzetra, Xsail, Avanir Pharms, Inc.)

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

Indication: Treatment of migraine with or without aura in adults.

Adverse Drug Reactions: The most common adverse reactions (incidence of greater than 2%) were abnormal taste, nasal discomfort, rhinorrhea and rhinitis.

Dose: Capsule in disposable nosepiece: 11mg sumatriptan as succinate salt. The recommended dosage of Onzetra is 22 mg of sumatriptan nasal powder (2 nose pieces), administered using the Xsail breath-powered delivery device.

Formulation: Inhalation (powder) via Xsail breath-powered delivery device.

Warnings/Contraindications: Contraindicated with history of coronary artery disease (CAD) or coronary vasospasm, Wolff-Parkinson-White syndrome or other cardiac accessory conditions pathway disorders. History of stroke, transient ischemic attack, or hemiplegic or basilar migraine, PVD, IBD and uncontrolled HTN are also contraindicated with this drug.

Amphetamine (Adzenys XR-ODT, Neos Therapeutics, Inc.)

Pharmacology: Central nervous system (CNS) stimulant

Indication: Treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients 6 years and older.

Dosage form: Extended-release orally disintegrating tablets available as 3.1-mg, 6.3-mg, 9.4-mg, 12.5-mg, 15.7-mg, 18.8-mg tablets.

Dose: Pediatric patients (ages 6 to 17 years): Starting dose is 6.3 mg once daily in the morning. Maximum dose is 18.8 mg once daily for patients 6 to 12 years, and 12.5 mg once daily for patients 13 to 17 years. Adults: 12.5 mg once daily in the morning.

Sumatriptan (Zembrace Symtouch, Dr Reddys Labs LTD)

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

Indication: Treatment of acute migraine with or without aura in adults

Dosage form: Injectable; injection

Dose: (3mg/ 0.5mL); prefilled, ready-to-use, single-dose disposable auto-injector containing 3mg of sumatriptan

Elbasvir and grazoprevir (Zepatier, Merck Sharp Dohme)

Pharmacology: Combination product containing elbasvir (HCV NS5A inhibitor) and grazoprevir (NS3/4A protease inhibitor).

Indication: Treatment of chronic HCV genotypes 1 or 4 infections; with or without ribavirin.

Dose form: Tablet; 50mg elbasvir/ 100mg grazoprevir

Dose: One tablet (50mg) orally once daily with or without food.

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