



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

Prasterone (Intrarosa, Endoceutics, Inc)

Pharmacology: Steroid.

Indication: Treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause.

Adverse Drug Reactions: Vaginal discharge, abnormal Pap smear.

Dose: 6.5 mg

Formulation: Vaginal insert.

Warnings/Contraindications: Undiagnosed abnormal genital bleeding.

Notes: Product should be inserted at bedtime.

NEW DRUG FORMULATIONS

Maraviroc (Selzentry, Viv Healthcare)

Pharmacology: CCR5 co-receptor antagonist.

Indication: Combination with other antiretroviral agents for the treatment of only CCR5-tropic HIV-1 infection in patients 2 years of age or older weighing at least 10 kg.

Dosage form: Oral solution.

Dose: 20 mg / mL.

Insulin degludec and liraglutide injection (Xultophy, Novo Nordisk, Inc.)

Pharmacology: Combination of long-acting human insulin analog and a glucagon-like peptide receptor agonist.

Indication: Improve glycemic control in adults with type 2 diabetes inadequately controlled on basal insulin or liraglutide.

Dosage form: Injection.

Dose: 16 units of insulin degludec and 0.5 mg of liraglutide. Maximum dose is 50 unites of insulin degludec and 1.8 mg of liraglutide.

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NEW DRUG FORMULATIONS (CONTINUED)

Insulin Glargine, Lixisenatide (Soliqua 100/33, Sanofi Aventis US)

Pharmacology: Long-acting human insulin analog with a glucagon-like peptide-1 receptor agonist.

Indication: Improve glycemic control in adults with type 2 diabetes inadequately controlled on basal insulin or lixisenatide.

Dosage form: Injection: 100 units of insulin glargine per mL and 33 mcg of lixisenatide per ML in a 3 mL single-patient use pen.

Dose: Variable, maximum daily dosage is 60 units (60 units of insulin glargine and 20 mcg of lixisenatide).

Doxylamine succinate and pyridoxine hydrochloride, extended-release tablets (Bonjesta, Duchesnay, Inc.)

Pharmacology: Antihistamine and vitamin B₆ analog.

Indication: Nausea and vomiting of pregnancy in women who do not respond to conservative management.

Dosage form: Extended-release tablets containing doxylamine succinate 20 mg and pyridoxine hydrochloride 20 mg.

Dose: Doxylamine succinate 20 mg and pyridoxine hydrochloride 20 mg.

Tenofovir alafenamide (Vemlidy, Gilead Sciences, Inc.)

Pharmacology: Hepatitis B virus (HBV) nucleoside analog reverse transcriptase inhibitor.

Indication: Chronic hepatitis B virus infection in adults with compensated liver disease.

Dosage form: Tablets, 25 mg.

Dose: 25 mg once daily with food.

NEW DRUG INDICATIONS

Atezolizumab (Tecentrig, Genentech Inc.)

Pharmacology: Antineoplastic agent, anti-pd-l1 monoclonal antibody.

New Indication: Locally advanced or metastatic urothelial carcinoma.

Dose: 1,200 mg administered IV every 3 weeks; continue until disease progression or unacceptable toxicity.

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