New Drug Approvals

**Intrarosa (prasterone)**

*Indication:* Moderate to severe pain during sexual intercourse (dyspareunia)

*Mechanism of Action:* Steroid

*Dosage Form(s):* Vaginal inserts

*Comments:* Intrarosa is a vaginally inserted steroid FDA-approved for the treatment of moderate to severe dyspareunia as a symptom of vulvar and vaginal atrophy caused by menopause. The recommended administration is one insert, containing 6.5 mg of prasterone, daily at bedtime. Women with undiagnosed, abnormal genital bleeding should not use Intrarosa. Additionally, because estrogen is a metabolite of prasterone, Intrarosa should be avoided or used cautiously in women with a known or suspected history of breast cancer. The most common adverse reactions reported with Intrarosa include vaginal discharge and abnormal Pap smears.

**Soliqua 100/33 (insulin glargine and lixisenatide)**

*Indication:* Type 2 diabetes

*Mechanism of Action:* Basal insulin analog (insulin glargine) and glucagon-like receptor peptide-1 (GLP-1) receptor agonist (lixisenatide)

*Dosage Form(s):* Injection for subcutaneous use

*Comments:* Soliqua 100/33 is a combination of long-acting insulin glargine (100 units/mL) and the GLP-1 receptor agonist lixisenatide (33 mcg/mL) FDA-approved to improve glycemic control in patients with type 2 diabetes inadequately controlled on either agent alone. It is not approved for type 1 diabetes or diabetic ketoacidosis. Soliqua should be started at a dose of 15 units insulin glargine/5 mcg lixisenatide once daily in patients inadequately controlled on less than 30 units of basal insulin or lixisenatide. Soliqua should be started at a dose of 30 units insulin glargine/10 mcg lixisenatide once daily in patients inadequately controlled on 30-60 units of basal insulin. Soliqua should be injected within the hour prior to the first meal of the day. The maximum dose of Soliqua is 60 units of insulin glargine with 20 mcg of lixisenatide. The same contraindications, warnings, precautions, and drug interactions for the individual agents apply to Soliqua. The most common adverse reactions reported with Soliqua include allergic reactions, diarrhea, headache, hypoglycemia, nasopharyngitis, nausea, and upper respiratory tract infections.

**Vemlidy (tenofovir alafenamide)**

*Indication:* Hepatitis B virus (HBV)

*Mechanism of Action:* HBV nucleoside analog reverse transcriptase inhibitor

*Dosage Form(s):* Oral tablets

*Comments:* Vemlidy is FDA-approved for the treatment of chronic HBV infection in adults with compensated liver disease. The recommended dosage is 25 mg once daily with food. Because Vemlidy delivers tenofovir more efficiently to hepatocytes, the dose and systemic exposure is lower than with Viread (tenofovir disoproxil fumarate). Vemlidy is not recommended for patients with HBV-HIV-1 coinfection, a CrCl < 15 mL/min, or decompensated hepatic impairment (Child-Pugh B or C). Vemlidy also carries a Boxed Warning describing an increased risk for lactic acidosis and severe hepatomegaly with steatosis as well as severe acute exacerbation of HBV upon discontinuation of therapy. Drugs affecting P-glycoprotein or breast cancer resistance protein (BCRP) activity may interfere with the absorption of Vemlidy. The most common adverse reactions reported with Vemlidy include abdominal pain, back pain, cough, fatigue, headache, and nausea.
The following shortages have been recently identified by the FDA. For additional information on drug shortages, please contact the Center for Drug Information & Evidence-Based Practice.

- Hydroxyamphetamine hydrobromide/tropicamide (Paremyd)
- Ranitidine injection

Current Shortages

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Creighton University’s Center for Drug Information & Evidence-Based Practice, in collaboration with PharMerica, is offering drug information services to all PharMerica-affiliated healthcare professionals.

Drug Information Consultation Service
Monday through Friday
830 am – 430 pm Central
Submit your questions online at http://creighton.edu/pharmerica
or call us at 1-800-561-3728
Voice mail service is available after hours

Contact us through our online submission form or call us for help with answering medication-related questions. Be sure to identify your affiliation with PharMerica, as this affords you priority status with our service. We will provide an evidence-based response within 24-48 hours. Let us help you provide top-quality resident care!