New Drug Approvals

Adlyxin (lixisenatide)

**Indication:** Type II diabetes

**Mechanism of Action:** Glucagon-like peptide-1 (GLP-1) receptor agonist

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

**Average Wholesale Price:** Unavailable

**Comments:** Adlyxin is FDA-approved as an adjunct to diet and exercise for glycemic control in adults with type II diabetes. It is injected subcutaneously into the abdomen, upper arm or thigh, and should be given within one hour prior to the first meal of the day. It is initiated at a dose of 10 mcg once daily for 14 days. Then, on day 15, the dose is increased to 20 mcg daily. Therapy should be promptly discontinued if pancreatitis is suspected. Adlyxin may cause hypoglycemia when taken with basal insulins or sulfonylureas. In such cases, lowering the dose of the sulfonylurea or basal insulin should be considered. In patients with renal impairment reporting serious adverse gastrointestinal reactions, renal function should be monitored. Further, Adlyxin should not be used in patients with end-stage renal disease. The most common adverse reactions reported with Adlyxin include nausea, vomiting, headache, diarrhea, dizziness, and hypoglycemia. Adlyxin delays gastric emptying and may affect the absorption of some oral medications. As such, medications particularly dependent on threshold concentrations (e.g., antibiotics) or medications in which a delay in effect is undesirable (e.g., oral pain medications) should be taken one hour prior to Adlyxin.

Qbrelis (lisinopril)

**Indication:** Hypertension, heart failure, and reduction of mortality in acute myocardial infarction (MI)

**Mechanism of Action:** Angiotensin-converting enzyme (ACE) inhibitor

**Dosage Form(s):** Oral solution

**Average Wholesale Price:** Unavailable

**Comments:** Qbrelis is FDA-approved for the treatment of hypertension, as an adjunct treatment option in heart failure, and for mortality benefit in acute MI. It is administered orally, and initial dosing depends on the indication for use. Impaired renal function decreases elimination of Qbrelis; therefore, dosing should be adjusted based on creatinine clearance. Qbrelis is contraindicated in patients with a history of angioedema or hypersensitivity. Further, it should not be given alongside aliskiren in patients with diabetes. During therapy, patients should be monitored for renal impairment, hypotension, hyperkalemia, and hepatic failure. The most common adverse reactions reported with Qbrelis therapy include headache, dizziness, cough, hypotension, and chest pain. Taking Qbrelis with diuretics may increase the risk for hypotension, while taking Qbrelis with nonsteroidal anti-inflammatory drugs may increase the risk for renal impairment. Concomitant therapy with an angiotensin II receptor antagonist may lead to renal impairment, hypotension, and hyperkalemia. Other drug interactions with Qbrelis are listed in the prescribing information.

Syndros (dronabinol)

**Indication:** Anorexia associated with weight loss in AIDS patients; chemotherapy-induced nausea and vomiting (CINV)

**Mechanism of Action:** Cannabinoid

**Dosage Form(s):** Oral solution

**Average Wholesale Price:** Unavailable

**Comments:** Syndros is FDA-approved for the treatment of anorexia associated with weight loss in adults with AIDS and for CINV in patients who have failed conventional treatments. The recommended adult dose for use in anorexia is 2.1 mg orally twice daily to be taken one hour before lunch and one hour before dinner. For CINV, the recommended starting dose is 4.2 mg/m². It should be administered 1 to 3 hours prior to chemotherapy and then 2 to 4 hours after chemotherapy for a total of 4 to 6 doses. The first dose should be given on an empty stomach at least 30 minutes before eating and subsequent doses can be taken without regard to meals. Syndros should not be used in individuals with a history of hypersensitivity to dronabinol or alcohol, or in those who have received disulfiram or metronidazole containing products in the last 14 days as Syndros contains alcohol and propylene glycol. Patients receiving Syndros should be monitored for neurological adverse reactions, hemodynamic instability, seizures or seizure like activity, and paradoxical nausea, vomiting, or abdominal pain. Patients should also be monitored while using inhibitors and inducers of CYP2C9 and CYP3A4 and highly protein-bound drugs as they may alter Syndros systemic exposure or the drug levels of concomitant medications. The most common adverse reactions reported with Syndros include dizziness, paranoid reaction, somnolence, abnormal thinking, abdominal pain, nausea, and vomiting.
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.

- Ceftazidime and avibactam (Avycaz) injection
- Dihydroergotamine mesylate injection
- Estradiol valerate injection

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
Voicemail service is available afterhours

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!

New Drug Approvals (continued)

Viekira XR (dasabuvir, ombitasvir, paritaprevir, ritonavir)

**Indication:** Hepatitis C

**Mechanism of Action:** NS5B polymerase inhibitor (dasabuvir), NS5A inhibitor (ombitasvir), NS3/4A protease inhibitor (paritaprevir), and CYP3A inhibitor (ritonavir)

**Dosage Form(s):** Oral tablets (extended release)

**Average Wholesale Price:** Unavailable

**Comments:** Viekira XR is FDA-approved for the treatment of chronic hepatitis C genotype 1a and 1b. It is indicated for use in patients without cirrhosis or with compensated cirrhosis. It is approved for use with ribavirin in patients with genotype 1a without cirrhosis or with compensated cirrhosis. The recommended dosage is 3 tablets containing 200 mg dasabuvir, 8.33 mg ombitasvir, 50 mg paritaprevir, and 33.33 mg ritonavir daily with a meal for 12 weeks. In patients with genotype 1a with compensated cirrhosis, the recommended duration is 24 weeks. Viekira XR is contraindicated for use in patients with moderate to severe hepatic impairment (Child-Pugh B or C). Patients should be monitored for hepatic decompensation and hepatic failure, especially within one to four weeks of initiating therapy. Viekira XR is contraindicated for use with moderate-to-strong CYP3A inducers and strong CYP2C8 inducers and inhibitors. The most common adverse events reported include fatigue, nausea, pruritus, skin reactions, insomnia, and asthenia.

**Xiidra (lifitegrast)**

**Indication:** Dry eye disease

**Mechanism of Action:** Lymphocyte function-associated antigen-1 (LFA-1) antagonist

**Dosage Form(s):** Ophthalmic solution

**Average Wholesale Price:** Unavailable

**Comments:** Xiidra is FDA-approved for the treatment of signs and symptoms of dry eye disease in adults. The recommended dosage of Xiidra is one drop of 5% (50 mg/mL) solution in each eye twice daily (approximately 12 hours apart). Patients wearing contact lenses should remove lenses right before applying drops and wait 15 minutes after instilling drops before reapplying lenses to the eyes. Xiidra is supplied as foil pouches containing strips of single-use containers. Each single-use container contains enough Xiidra to treat each eye one time. If there is any remaining solution in the container after applying 1 drop in each eye, dispose of the container — do not save any unused Xiidra for later use. Xiidra containers should be stored in the original foil pouches to protect from excessive light exposure. There are no known drug-drug or drug-disease contraindications for Xiidra. The most common side effects include eye irritation or blurred vision when the drops are applied and a disturbance in taste (dysgeusia).

Safety Updates

**Fluoroquinolones**

The FDA recently strengthened the existing warning about the risk of disabling and potentially permanent side effects to the tendons, muscles, joints, nerves and central nervous system associated with systemic fluoroquinolone use. In most cases, these side effects have occurred within hours to weeks after starting therapy. Health care professionals are advised that, due to these side effects, patients diagnosed with acute bacterial sinusitis, acute exacerbation of chronic bronchitis, and uncomplicated urinary tract infections should only be treated with fluoroquinolones when no other treatment options are available.

Current Shortages

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.

- Ceftazidime and avibactam (Avycaz) injection
- Dihydroergotamine mesylate injection
- Estradiol valerate injection