The FDA recently strengthened the existing warning about the risk of kidney injury associated with the use of canagliflozin and dapagliflozin. Health care professionals should consider factors that may predispose patients to acute kidney injury before initiating these SGLT2 inhibitors. These include decreased blood volume, chronic kidney disease, congestive heart failure, and concomitant use of angiotensin-converting enzyme inhibitors, angiotensin II receptor blockers, or nonsteroidal anti-inflammatory drugs. Additionally, the FDA recommends that kidney function be monitored periodically in patients taking canagliflozin or dapagliflozin.

The FDA recently published a safety communication warning health care professionals about the risk of serous heart problems related to the use of high doses of OTC or prescription loperamide. Health care professionals should be aware of the potential for intentional misuse of loperamide to self treat opioid withdrawal or to achieve euphoric effects. Serious cardiac events which may be explained by loperamide abuse or misuse include QT interval prolongation, Torsades de Pointes or other ventricular arrhythmias, syncope, and cardiac arrest.
New Drug Approvals (continued)

Rayaldee (calcifediol)

*Indication:* Secondary hyperparathyroidism in stage 3 or 4 chronic kidney disease

*Mechanism of Action:* Vitamin D3 analog

*Dosage Form(s):* Extended-release capsules

*Average Wholesale Price:* Unavailable

*Comments:* Rayaldee is a vitamin D3 analog indicated for the treatment of secondary hyperparathyroidism in adults with stage 3 or 4 chronic kidney disease and serum total 25-hydroxyvitamin D levels less than 30 ng/mL. It is not indicated for end stage renal disease or dialysis. The initial dose is 30 mcg at bedtime. Serum calcium should be below 9.8 mg/dL before initiating treatment, and serum calcium, phosphorus, 25-hydroxyvitamin D, and intact PTH should be monitored three months after starting therapy or before changing dose. The dose of Rayaldee should be increased to 60 mcg daily if intact PTH is above treatment goal, while treatment should be suspended if intact PTH is persistently abnormally low, serum calcium is consistently above normal, or hydroxyvitamin D is consistently above 100 ng/mL. Patients should be monitored for hypercalcemia and adynamic bone disease. Co-administration of Rayaldee with P450 inhibitors may alter serum levels of calcifediol. Use with thiazide diuretics may increase the risk for hypercalcemia, and cholestyramine may impair the absorption of calcifediol. The most common adverse reactions reported with Rayaldee include anemia, nasopharyngitis, increased blood creatinine, dyspnea, congestive heart failure, and constipation.

Note: This is not a comprehensive list. New drug approvals are reviewed for agents most relevant to the long term care population.

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.

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Safety Updates (continued)

OTC Antacids with Aspirin - Bleeding Risk

The FDA recently published a safety communication warning of the potential for serious bleeding in patients taking nonprescription aspirin-containing antacid products to treat heartburn and indigestion. The FDA has continued to receive reports of serious bleeds in patients taking these medications despite warnings on the drug labels. Patients should be informed of this concern and encouraged to report any side effects associated with the use of aspirin-containing products to their health care providers.

Zecuity (Sumatriptan) Patch - Burns and Scars

The FDA recently published an alert announcing that the potential for serious burns and scars associated with the use of Zecuity (sumatriptan) patch for migraine headaches was being investigated. Based on this announcement, Teva Pharmaceuticals, the manufacturer of Zecuity, decided to suspend sales and distribution of this product. Until more information is known, health care providers should stop prescribing Zecuity. Patients should stop using any remaining patches and contact their provider to discuss alternative therapies.

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.

- Piperacillin and tazobactam (Zosyn) injection