The FDA recently published a safety communication warning that rare but serious allergic reactions have been reported in patients using antiseptics containing chlorhexidine gluconate. A warning describing this concern will be added to the Drug Facts label of all over-the-counter products containing chlorhexidine gluconate. Before recommending products containing this agent, health care providers should ask patients about their history of allergic reactions to antiseptic products. If an allergy to chlorhexidine gluconate is documented or suspected, alternative agents such as povidone-iodine, alcohols, benzalkonium chloride, benzethonium chloride, or parachlorometaxylenol may be considered.

March 2017

New Drug Approvals

**Emflaza (deflazacort)**

*Indication:* Duchenne muscular dystrophy (DMD)

*Mechanism of Action:* Corticosteroid

*Dosage Form(s):* Oral tablet and oral suspension

*Comments:* Emflaza is an orally administered corticosteroid FDA-approved for the treatment of DMD in patients 5 years of age and older. It is given once daily at a dose of around 0.9 mg/kg/day. In the event that Emflaza is given for more than a few days, the dose should be decreased gradually before discontinuation. Patient taking Emflaza should be monitored for alterations in endocrine function, immunosuppression, elevated blood pressure, elevated serum sodium, decreased potassium, gastrointestinal perforation, mood disturbances, and skin rash. The dose of Emflaza should be cut to one-third in patients also taking moderate or strong CYP3A4 inhibitors, and the use of moderate or strong CYP3A4 inducers should not be taken with Emflaza. The most common adverse reactions reported with this drug include cushingoid appearance, weight gain, increased appetite, upper respiratory tract infections, cough, pollakiuria, hirsutism, central obesity, and nasopharyngitis.

**Parsabiv (etelcalcetide)**

*Indication:* Hyperparathyroidism

*Mechanism of Action:* Calcium-sensing receptor agonist

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

*Comments:* Parsabiv is FDA-approved for the treatment of secondary hyperparathyroidism in adults with chronic kidney disease. It is initially dosed as a 5 mg IV bolus given three times weekly at the end of hemodialysis. Maintenance doses typically range from 2.5 mg to 15 mg three times weekly and are titrated based on parathyroid hormone and corrected serum calcium response. Patients receiving Parsabiv should be monitored for hypocalcemia, worsening heart failure, upper gastrointestinal bleeding, and adynamic bone. The most common adverse reactions reported with Parsabiv include hypocalcemia, muscle spasms, diarrhea, nausea, vomiting, heachace, and paresthesia.

**Qtern (dapagliflozin and saxagliptin)**

*Indication:* Type 2 diabetes

*Mechanism of Action:* Sodium-glucose cotransporter 2 (SGLT-2) inhibitor and dipeptidyl peptidase-4 (DPP-4) inhibitor

*Dosage Form(s):* Oral tablets

*Comments:* Qtern is an SGLT-2 inhibitor and DPP-4 inhibitor combination product FDA-approved for the management of glycemic control in patients inadequately controlled on dapagliflozin or already taking both dapagliflozin and saxagliptin. The recommended dose is 10 mg dapagliflozin/5 mg saxagliptin once daily in the morning. Patients with eGFR <60 mL/min/1.73m² should not take this drug. Qtern carries the same contraindications, warnings, and precautions as the individual agents. This product should not be taken with strong CYP3A4/5 inhibitors. The most common adverse reactions reported with Qtern include upper respiratory tract infections, urinary tract infections, and dyslipidemia. Geriatric patients taking this product may be at a higher risk of renal impairment and volume-depletion-related adverse reactions.
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.

- Albuterol sulfate inhalation solution (0.021%, 0.042%, and 0.5%)
- Belatacept (Nulojix) lyophilized powder for injection
- Labetalol hydrochloride injection
- Piperacillin and tazobactam (Zosyn) injection
- Sincalide (Kinevac) lyophilized powder for injection
- Sodium bicarbonate 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!