The FDA recently announced that safety-related labeling changes will be required in order to inform healthcare professionals and patients of the serious risks associated with the combined use of certain opioids and benzodiazepines. Boxed warnings and medication guides will be required to state risks, including extreme sleepiness, respiratory depression, coma, and death.

Healthcare professionals are advised to limit prescribing opioids with benzodiazepines or other CNS depressants, including alcohol, only in cases where alternatives are not available. If these medications must be prescribed, the lowest possible dose for the shortest possible duration should be used.

### New Drug Approvals

**Erelzi (etanercept-szzz)**

*Indication:* Rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, and plaque psoriasis

*Mechanism of Action:* Tumor necrosis factor (TNF) blocker

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

*Comments:* Erelzi is biosimilar to Enbrel (etanercept) and was FDA-approved for the treatment of multiple inflammatory diseases as listed above. It is administered by subcutaneous injection and initial dosing depends on the indication for use. Erelzi carries a Boxed Warning describing an increased risk for serious infections and malignancies. A TB test is required prior to starting therapy. Erelzi is contraindicated in patients with sepsis and should not be given with live vaccines. Additionally, it should be used cautiously in patients with heart failure or diabetes and should not be given with the following medications: cyclophosphamide, abatacept, or kinerep. The most common adverse effects reported with Erelzi include infections and injection site reactions. Adverse effects reported with Erelzi were similar in both the adult and geriatric population. The effects of hepatic or renal impairment on the pharmacokinetics and safety of Erelzi have not been adequately assessed to date.

**Fionase Sensimist (fluticasone furoate)**

*Indication:* Seasonal and perennial allergies

*Mechanism of Action:* Corticosteroid

*Dosage Form(s):* Nasal spray

*Comments:* Fionase Sensimist is FDA-approved to treat both seasonal and perennial symptoms of allergic rhinitis. This approval is an Rx-to-OTC switch and a re-branding of the prescription product Veramyst. The nasal spray medication, which delivers 27.5 mcg active medication per 50 mcg actuation, will be available OTC in early 2017. Adults and adolescents > 12 years old should use two sprays per nostril daily, and children 2-12 years old should use one spray per nostril daily. Patients who have recently had nasal ulcers, nasal surgery, or nasal trauma should not use this product. Children using this product should be monitored by a physician as corticosteroids can reduce growth velocity in children. The most common adverse effects are headache, epistaxis, pharyngolaryngeal pain, nasal ulceration, back pain, pyrexia, and cough. Hypercorticism and adrenal suppression can occur with very high doses or in highly susceptible individuals. Potent inhibitors of cytochrome P450 (CYP3A4) or hepatic impairment can increase the patient’s exposure to this medication.

**Sustol (granisetron)**

*Indication:* Chemotherapy-induced nausea and vomiting

*Mechanism of Action:* Serotonin-3 (5-HT3) receptor antagonist

*Dosage Form(s):* Extended-release injection (subcutaneous)

*Comments:* Sustol is FDA-approved for prevention of acute and delayed nausea and vomiting associated with initial and repeat course of moderately emetogenic chemotherapy or anthracycline and cyclophosphamide combination chemotherapy regimens. Sustol is intended for subcutaneous use and administration by a healthcare professional. It should be administered via a slow sustained injection over 20-30 seconds in the skin of the back of the arm or the skin of the abdomen at least 1 inch away from the umbilicus. The recommended dose for adults is 10 mg administered as a single injection, given at least 30 minutes before day 1 of emetogenic chemotherapy. Sustol should not be dosed more than once every 7 days or used with chemotherapy for more than 6 months. Patients with moderate renal impairment (CrCl 30-59 mL/min) should not have Sustol administered more than once every 14 days, and patients with severe renal impairment (CrCl < 30 mL/min) should avoid using Sustol. Patients receiving Sustol should be monitored for constipation, injection site reactions, hypersensitivity reactions, and serotonin syndrome. No overall differences in safety or effectiveness have been observed between geriatric patients and younger patients receiving Sustol; however, this does not rule out differences in sensitivity to Sustol in older individuals.
New Drug Approvals
(continued)

Troxyca ER (naltrexone and oxycodone)

**Indication:** Pain

**Mechanism of Action:** Combination opioid antagonist and opioid agonist

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

**Comments:** Troxyca ER is FDA-approved for the management of severe pain that requires daily, around-the-clock, long-term opioid treatment and for which alternative treatments options are inadequate. It should not be used as an as-needed analgesic. Troxyca ER is considered “abuse-deterrent” in that it contains a naltrexone core which remains intact when swallowed whole. However, in the event that Troxyca ER capsules are chewed or crushed, the naltrexone component is released and counteracts the effects of oxycodone. This could also precipitate opioid withdrawal in some patients. Dosing of Troxyca ER should be individualized based on the severity of pain, patient response, prior analgesic experience, and risk factors for addiction, abuse, and misuse. The lowest effective dose for the shortest duration consistent with individual patient treatment goals should be utilized. Geriatric patients should start at the low end of the dosing range and be monitored closely for respiratory depression. Patients who have hepatic or renal impairment should be monitored closely for CNS or respiratory depression and for signs of withdrawal. Patients should be instructed to swallow Troxyca ER capsules whole to avoid exposure to potentially fatal dose of oxycodone. Serious, life-threatening, or fatal respiratory depression may occur. Patients should be monitored closely, especially upon initiation or following a dose increase. Concomitant treatment with CYP3A4 inhibitors, or the discontinuation of CYP3A4 inducers, may result in fatal overdose of the oxycodone component.

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.

**Drug Information Consultation Service**
Monday through Friday
830 am – 430 pm Central
Submit your questions online at [http://creighton.edu/pharmerica](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!

Safety Updates
(continued)

**Programmable Syringe Pumps**

The FDA recently published a safety communication warning about problems with fluid flow continuity at low infusion rates in all programmable syringe pumps. Serious adverse events such as abnormal or unstable blood pressure and anxiety from loss of sedation have been reported in association with lack of flow continuity. Overall, the FDA considers the benefits of programmable syringe pumps to exceed their risks. A request from the FDA to manufacturers has been made for labeling changes regarding concerns about flow continuity. For additional information see the FDA’s Infusion Pump Risk Reduction Strategies available at: [http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/GeneralHospitalDevicesandSupplies/InfusionPumps/ucm202498.htm](http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/GeneralHospitalDevicesandSupplies/InfusionPumps/ucm202498.htm)

Current Shortages
(continued)

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.

- Penicillin G benzathine / penicillin G procaine (Bicillin C-R) injection
- Estradiol valerate injection
- Ceftazidime and avibactam (Avycaz) injection