Approvals & Updates

February 2022

Safety Updates

FDA warns about dental problems with buprenorphine medicines dissolved in the mouth to treat opioid use disorder and pain

The FDA recently published a safety communication warning of dental problems associated with orally dissolving medications that contain buprenorphine. The dental complications, some of which have been reported by patients with a healthy dental history, include tooth decay, cavities, oral infections, and loss of teeth. As such, the FDA is requiring manufacturers of buprenorphine-containing mediations that dissolve orally to include a new warning regarding the risk of dental complications, as well as strategies to maintain or improve oral health while using these medications, to the prescribing information and patient Medication Guide. It is important health care providers know that the benefits of buprenorphine when used in combination with counseling and other behavioral therapies outweigh the associated risks when treating opioid use disorder (OUD); however, providers should also encourage patients to attend regular dental checkups and refer patients to dental care providers.

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New Drug Approvals

Cibinqo (abrocitinib)

Indication: Atopic dermatitis

Mechanism of Action: Janus kinase (JAK) inhibitor

Dosage Form(s): Tablets

Comments: Cibinqo is FDA-approved for treating refractory, moderate-to-severe atopic dermatitis in adults whose disease is improperly controlled with other systemic medications, including biologics, or when those therapies are not recommended. Before beginning Cibinqo, a tuberculosis infection evaluation and viral hepatitis screening should be conducted, and complete blood count (CBC) levels should be evaluated. Cibinqo should be taken as 100mg by mouth around the same time once daily, but if a proper response is still not achieved after 12 weeks, the dose may be increased to 200mg once daily. Cibinqo carries a Boxed Warning for serious infections, mortality, malignancy, major adverse cardiovascular vents (MACE), and thrombosis. Cibinqo carries labeled warnings for laboratory abnormalities and immunizations. CBC, hemoglobin/hematocrit, liver function tests, hepatitis serology, cholesterol profile, serum creatinine/BUN, and signs and symptoms of infection, such as active tuberculosis, should all be monitored while on Cibinqo. Co-administration of Cibinqo with moderate to strong CYP2C19 and CYP2C9 inhibitors or strong CYP2C19 and CYP2C9 inducers should be avoided. However, if necessary, in patients on strong CYP2C19 inhibitors, the maximum dose of Cibinqo should be 50mg daily or 100mg daily if unresponsive to 50mg daily. Additionally, patients on P-glycoprotein substrates with a narrow therapeutic index should be closely monitored and may require dose adjustments if also taking Cibinqo. The most common adverse reactions (≥1%) reported with Cibinqo 100mg and 200mg were nasopharyngitis, nausea, headache, herpes simplex, increased blood creatinine phosphokinase, dizziness, urinary tract infection, fatigue, acne, vomiting, oropharyngeal pain, influenza, and gastroenteritis.

New Drug Approvals, Continued

Kimmtrak (tebentafusp-tebn)

Indication: Metastatic uveal melanoma

Mechanism of Action: gp100 peptide-HLA-directed CD3 T cell engager

Dosage Form(s): Intravenous (IV) injection

Comments: Kimmtrak is FDA-approved for treating HLA-A*02:01-positive adults with unresectable or metastatic uveal melanoma. Kimmtrak should be injected IV over 15 to 20 minutes as 20mcg on Day 1, 30mcg on Day 8, 68mcg on Day 15, and 68mcg once weekly thereafter until disease progression or toxicity occurs. Kimmtrak carries a Boxed Warning for cytokine release syndrome, so patients should be monitored for ≥16 hours after the first three infusions and as clinically necessary thereafter. Kimmtrak carries labeled warnings for skin reactions, elevated liver enzymes, and embryo-fetal toxicity. Alanine aminotransferase (ALT), aspartate aminotransferase (AST), and total bilirubin should be monitored throughout therapy, as well as signs and symptoms of skin reactions and cytokine release syndrome. No specific drug interactions are associated with Kimmtrak but increases in specific proinflammatory cytokines can suppress CYP450 enzyme activities. The most common adverse reactions (≥30%) and laboratory abnormalities (≥50%) reported with Kimmtrak were cytokine release syndrome, rash, pyrexia, pruritus, fatigue, nausea, chills, abdominal pain, edema, hypotension, dry skin, headache, and vomiting and decreased lymphocytes, increased creatinine, increased glucose, increased AST, increased ALT, decreased hemoglobin, and decreased phosphate.

Quviviq (daridorexant)

Indication: Insomnia

Mechanism of Action: Orexin receptor antagonist

Dosage Form(s): Tablets

Comments: Quviviq is FDA-approved for treating insomnia associated with difficulties falling asleep and/or maintaining sleep in adults. Quviviq should be taken as 25mg to 50mg by mouth once a night within 30 minutes before going to bed but at least 7 hours before planning to be awake. Consumption with or soon after a meal may delay time to sleep onset. Quviviq carries labeled warnings for CNS-depressant effects and daytime impairment, worsening of depression/suicidal ideation, sleep paralysis, hypnagogic/hypnopompic hallucinations, and cataplexy-like symptoms, complex sleep behaviors, compromised respiratory function, and need to evaluate for co-morbid diagnoses. Suicide risk may need to be monitored in patients taking Quviviq. Co-administration of Quviviq with strong CYP3A4 inhibitors and/or moderate or strong CYP3A4 inducers should be avoided. Additionally, in patients taking moderate CYP3A4 inhibitors, the maximum dose of Quviviq should be 25mg. The most common adverse reactions (≥5%) reported with Quviviq were headache and somnolence or fatigue.

Current Drug Shortages

The following shortages have been recently identified by the FDA:

- Bumetadine injection
- Dextrose 5% injection
- Dextrose 25% injection
- Potassium chloride concentrate injection

For additional information on drug shortages, please contact the Center for Drug Information & Evidence-Based Practice.

New Drug Approvals, Continued

Vabysmo (faricimab-svoa)

Indication: Neovascular age-related macular degeneration (nAMD), diabetic macular edema

Mechanism of Action: Vascular endothelial growth factor (VEGF) and angiopoietin-2 (Ang-2) inhibitor

Dosage Form(s): Intravitreal injection

Comments: Vabysmo is FDA-approved for treating nAMD and diabetic macular edema. Vabysmo should be dosed based on the indication. For patients with nAMD, 6mg should be injected intravitreally every 4 weeks for the first four doses. Optical coherence tomography and visual acuity evaluations should be conducted 8 and 12 weeks after to determine whether a 6mg dose should be given on one of three following regimens: 1) Weeks 28 and 44; 2) Weeks 24, 36, and 48; or 3) Weeks 20, 28, 36, and 44. For patients with diabetic macular edema, 6mg should be injected intravitreally every 4 weeks for at least four doses. If edema resolves after four doses based on the central subfield thickness of the macula, dosing intervals can be adjusted. Vabysmo carries labeled warnings for endophthalmitis and retinal detachments, increase in intraocular pressure, and thromboembolic events. Intraocular pressure and perfusion of the optic nerve should be monitored throughout therapy. No drug interactions with Vabysmo were discussed. The most common adverse reaction (≥5%) reported with Vabysmo was conjunctival hemorrhage.

Recently Approved Drug Combinations, Dosage Forms/Strengths, Indications, and Biosimilars

Brand (Generic)	Indication	Mechanism of Action	Dosage Form	Comments
Ryaltris (Olopatadine and mometasone furoate	Allergic rhinitis	Histamine-1 receptor inhibitor and corticosteroid	Nasal spray	New combination

Creighton University Center for Drug Information & Evidence-Based Practice

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