Approvals & Updates

July 2021

Safety Updates

FDA warns that vapors from alcohol-based hand sanitizers can have side effects

The FDA recently published a safety communication warning of side effects associated with alcohol-based hand sanitizers, such as headache, nausea, and dizziness. The side effects are most likely to due to vapors from the hand sanitizer, potentially when used in enclosed spaces or rooms with poor air circulation. While most side effects have been minor in severity, some have required medical care. No changes are being made to the Drug Facts label for hand sanitizers, but the FDA is continuing to monitor adverse effect reports associated with hand sanitizers. In the meantime, healthcare professionals and consumers are advised to use hand sanitizer in well-ventilated spaces.

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New Drug Approvals

Aduhelm (aducanumab-avwa)

Indication: Alzheimer's disease

Mechanism of Action: Amyloid beta-directed monoclonal antibody

Dosage Form(s): Intravenous (IV) injection

Comments: Aduhelm is FDA-approved for treating Alzheimer's disease. Aduhelm should be administered IV over about 1 hour every four weeks and ≥21 days apart. It should first be slowly titrated as outlined below.

- IV infusion 1 and 2: Aduhelm 1mg/kg
- IV infusion 3 and 4: Aduhelm 3mg/kg
- IV infusion 5 and 6: Aduhelm 6mg/kg
- IV infusion 7 and beyond: Aduhelm 10mg/kg

Following initial titration, the recommended maintenance dose is 10mg/kg. Aduhelm carries labeled warnings for amyloid-related imaging abnormalities (ARIA) and hypersensitivity reactions. A brain magnetic resonance imaging (MRI) should be obtained within 1 year of starting Aduhelm and before the 7th (first dose of 10mg/kg) and 12th (sixth dose of 10mg/kg) infusions. Aduhelm has no specific drug interactions outlined. The most common adverse reactions (≥10% and more than placebo) reported with Aduhelm were ARIA-edema, headache, ARIA-H microhemorrhage, ARIA-H superficial siderosis, and falls.

New Drug Approvals, Continued

Brexafemme (ibrexafungerp)

Indication: Vulvovaginal candidiasis (VVC)

Mechanism of Action: Triterpenoid antifungal

Dosage Form(s): Tablets

Comments: Brexafemme is FDA-approved for treating VVC in adult and post-menarchal pediatric females. Brexafemme should be taken as 300mg by mouth about 12 hours apart for one day and without regard to meals. Brexafemme carries a labeled warning for risk of fetal toxicity. Pregnancy status should be obtained prior to starting therapy. The dose of Brexafemme should be reduced to 150mg twice daily for one day if co-administered with strong CYP3A inhibitors. Concomitant administration of Brexafemme with strong or moderate CYP3A inducers should be avoided. The most common adverse reactions (≥2%) reported with Brexafemme were diarrhea, nausea, abdominal pain, dizziness, and vomiting.

Prevnar 20 (pneumococcal 20-valent conjugate vaccine)

Indication: Pneumococcal disease prophylaxis

Mechanism of Action: Vaccine

Dosage Form(s): Intramuscular (IM) injection

Comments: Prevnar 20 is FDA-approved for preventing pneumonia and invasive disease due to *Streptococcus pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 8, 9V, 10A, 11A, 12F, 14, 15B, 18C, 19A, 19F, 22F, 23F, and 33F in adults (≥18 years). Prevnar should be administered as 0.5mL IM. Prevnar 20 carries labeled warnings for management of acute allergic reactions and altered immunocompetence. Patients on immunosuppressive therapy may not experience an optimal response to Prevnar 20, and administration of Pneumovax 23 1-5 years before Prevnar 20 caused diminished opsonophagocytic activity (OPA) geometric mean titers to Prevnar 20 when compared with those who received Prevnar 13 ≥6 months before or Prevnar 13 followed by Pneumovax 23 (with the last dose of Pneumovax 23 given ≥1 year before Prevnar 20). The most common adverse reactions (>10%) reported with Prevnar 20 in adults 18-59 years were pain at injection site, muscle pain, fatigue, headache, and arthralgia and injection site swelling. The most common adverse reactions (>10%) reported with Prevnar 20 in adults ≥60 years were pain at injection site, muscle pain and fatigue, headache, and arthralgia.

New Drug Approvals, Continued

Ryplazim (plasminogen, human-tvmh)

Indication: Plasminogen deficiency type 1

Mechanism of Action: Plasma-derived human plasminogen

Dosage Form(s): IV injection

Comments: Ryplazim is FDA-approved for treating individuals with plasminogen deficiency type 1. Ryplazim should be administered as 6.6mg/kg IV every 2 to 4 days. Frequency of administration may need to be adjusted depending on plasminogen activity level and/or resolution of lesions. Ryplazim carries labeled warnings for bleeding, tissue sloughing, transmission of infectious agents, hypersensitivity reactions, neutralizing antibodies, and laboratory abnormalities. Patients with bleeding diatheses or taking anticoagulants, antiplatelet drugs, or other agents that could interfere with normal coagulation should be monitored for bleeding during and for 4 hours following Ryplazim infusion. Patients at risk for respiratory distress due to tissue sloughing should be monitored for ≥4 hours following the first Ryplazim dose. Additionally, the development of new or recurrent lesions (indicative of loss of efficacy) and plasminogen activity trough levels should be monitored throughout therapy. Ryplazim has no specific drug interactions outlined. The most common adverse reactions (≥10%) reported with Ryplazim were abdominal pain, bloating, nausea, fatigue, extremity pain, hemorrhage, constipation, dry mouth, headache, dizziness, arthralgia, and back pain.

Tembexa (brincidofovir)

Indication: Smallpox

Mechanism of Action: Orthopoxvirus nucleotide analog DNA polymerase inhibitor

Dosage Form(s): Tablets, oral suspension

Comments: Tembexa is FDA-approved for treating adults, children, and neonates with human smallpox disease due to variola virus. Tembexa oral suspension and tablets should be dosed as outlined below.

- Oral suspension (10mg/mL)
  - Weight <10kg: 6mg/kg once weekly for 2 doses (on Days 1 and 8)
  - Weight 10kg to <48kg: 4mg/kg once weekly for 2 doses (on Days 1 and 8)
  - Weight ≥48kg: 200mg (20 mL) once weekly for 2 doses (on Days 1 and 8)
- Tablets (100mg)
  - Weight ≥48kg: 200mg (two 100mg tablets) once weekly for 2 doses (on Days 1 and 8)

The oral suspension should be shaken before used and taken on an empty stomach, and tablets may be taken on an empty stomach or with a low-fat meal. Tembexa carries a Boxed Warning for increased risk for mortality when used for longer duration, as such it should not be used for any indication besides smallpox. Tembexa carries labeled warnings for elevations in hepatic transaminases and bilirubin, diarrhea and other gastrointestinal adverse events, co-administration with related products, embryo-fetal toxicity, carcinogenicity, and male infertility. Liver function tests should be monitored before and during therapy, and diarrhea and other gastrointestinal side effects should be monitored throughout therapy. Additionally, pregnancy status should be confirmed prior to starting Tembexa. Concomitant administration of Tembexa with OATP1B1 or 1B3 inhibitors should be avoided; however, if not possible, administration of OATP1B1 or 1B3 inhibitors should be held for ≥3 hours following Tembexa administration, and increased monitoring for adverse effects is advised. The most common adverse reactions (≥2%) reported with Tembexa were diarrhea, nausea, vomiting, and abdominal pain.

Current Drug Shortages

The following shortages have been recently identified by the FDA:

- Mepivacaine hydrochloride injection

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

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

Brand (Generic)	Indication	Mechanism of Action	Dosage Form	Comments
Astepro Allergy (Azelastine)	Allergic rhinitis	Histamine H1-receptor antagonist	Nasal solution	New OTC
Rezipres (Ephedrine Hydrochloride)	Hypotension	Alpha- and beta adrenergic agonist	IV injection	New strength
Rylaze (Asparginase erwinia chrysanthemi [recombinant] rywn)	Acute lymphoblastic leukemia (ALL) and lymphoblastic lymphoma (LBL)	Asparagine specific enzyme	IM injection	Recombinant formulation
Soaanz (Torsemide)	Edema	Loop diuretic	Tablets	New strength
Verkazia (Cyclosporine)	Vernal keratoconjunctivitis	Calcineurin inhibitor	Ophthalmic emulsion	New strength
Wegovy (Semaglutide)	Obesity	Glucagon-like peptide 1 (GLP-1) receptor agonist	Subcutaneous injection	New indication

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