Approvals & Updates

November 2020

PharMerica®

New Drug Approvals

Veklury (remdesivir)

Indication: Coronavirus disease 2019 (COVID-19)

Mechanism of Action: SARS-CoV-2 nucleotide analog RNA polymerase inhibitor

Dosage Form(s): Lyophilized powder for injection, solution for injection

Comments: Veklury is FDA-approved for treating COVID-19 in adult and pediatric patients (≥12 years, weighing ≥40kg) requiring hospitalization. It should only be given in a hospital or healthcare setting adept to delivering acute care similar to inpatient hospital care. Veklury should be intravenously infused over 20 to 120 minutes as a 200mg single loading dose on the first day followed by 100mg once-daily maintenance doses starting on the second day. The recommended treatment duration is 5 days for patients who do not require invasive mechanical ventilation and/or ECMO, but if these patients do not clinically improve, Veklury therapy can be lengthened to up to 5 additional days. On the other hand, patients who require invasive mechanical ventilation and/or ECMO should be treated for a total of 10 days. Veklury carries labeled warnings for hypersensitivity including infusion-related and anaphylactic reactions, increased risk of transaminase elevations, and risk of reduced antiviral activity when co-administered with chloroquine phosphate or hydroxychloroquine sulfate. Prior to initiating Veklury and during therapy, eGFR and hepatic function tests (ALT, AST, bilirubin, alkaline phosphatase, prothrombin time) should be determined and monitored. Additionally, signs and symptoms of hypersensitivity including infusion-related reactions should be monitored throughout therapy. While no drug interaction studies between Veklury and other concomitant drugs have been performed in humans, concomitant administration of Veklury with chloroquine phosphate or hydroxychloroquine sulfate should be avoided, as chloroquine demonstrated an antagonistic effect on Veklury's intracellular metabolic activation and antiviral activity. Furthermore, Veklury and its metabolites are substrates and/or inhibitors of various metabolizing enzymes and transporters in vitro; however, the clinical significance of this is yet to be determined. The most common adverse reactions (≥5%) reported were nausea, increased ALT, and increased AST.

Safety Alerts

FDA recommends avoiding use of NSAIDs in pregnancy at 20 weeks or later because they can result in low amniotic fluid

The FDA recently published a safety communication advising healthcare professionals and pregnant women to avoid the intake of NSAIDs around 20 weeks or later during pregnancy, because rare but serious renal complications in the unborn baby may occur. These renal complications can reduce the amount of amniotic fluid surrounding the baby, because it is after 20 weeks of pregnancy that an unborn baby's kidneys make the most amniotic fluid, which serves to protect them and help develop the lungs, digestive system, and muscle. This warning applies to both prescription and OTC NSAIDs. Manufacturers of prescription NSAIDs are required to make changes to prescribing information that explains this risk of renal complications in unborn babies that cause reduced amniotic fluid, and the FDA plans to update the Drug Facts labels of OTC NSAIDs indicated for adults. If NSAIDs are judged to be essential in pregnant patients after 20 weeks, healthcare professionals are advised to use the lowest effective dose for the shortest duration and consider ultrasound monitoring of amniotic fluid if NSAID therapy lasts longer than 48 hours.

Current Drug Shortages

The following shortage has been recently identified by the FDA:

- Cysteamine hydrochloride ophthalmic solution
- Hydrocortisone tablets

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

Recently Approved Drug Combinations, Dosage Forms, and Biosimilars

Brand (Generic)	Indication	Mechanism of Action	Dosage Form	Comments
Bronchitol (Mannitol)	Cystic fibrosis	Unknown	Inhalation powder	New indication
Eysuvis (loteprednol etabonate)	Dry eye disease	Corticosteroid	Ophthalmic suspension	New indication

Creighton University Center for Drug Information & Evidence-Based Practice

Drug Information Consultation Service

Monday through Friday

7:30am-3:30pm Central

1-800-561-3728

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