Approvals & Updates

February 2021

PharMerica

New Drug Approvals

Lupkynis (voclosporin)

Indication: Lupus nephritis

Mechanism of Action: Calcineurin inhibitor immunosuppressant

Dosage Form(s): Capsules

Comments: Lupkynis is FDA-approved, in combination with a background immunosuppressive therapy regimen, for treating adults with active lupus nephritis. Lupkynis is given as 23.7mg by mouth twice daily on an empty stomach. Estimated glomerular filtration rate (eGFR) and blood pressure should be established prior to starting Lupkynis and monitored regularly after initiating, as Lupkynis may need to be dose adjusted, discontinued, or not considered depending on the results. Lupkynis carries a Boxed Warning for malignancies and serious infections, so patients should be examined for skin changes, advised to avoid or limit sun exposure, and monitored for the development of infection. Lupkynis carries labeled warnings for nephrotoxicity, hypertension, neurotoxicity, hyperkalemia, QT prolongation, immunizations, and pure red cell aplasia. In addition to regularly monitoring eGFR and blood pressure while on Lupkynis, serum creatinine, blood urea nitrogen (BUN), serum potassium, liver function tests, neurologic abnormalities, and potential drug interactions should also be monitored. Concomitant administration of Lupkynis with strong CYP3A4 inhibitors is contraindicated, and concomitant administration with moderate CYP3A4 inhibitors or strong and moderate CYP3A4 inducers should be avoided. If coadministration with moderate CYP3A4 inhibitors is unavoidable, Lupkynis should be reduced to 15.8mg in the morning and 7.9mg in the evening. Specific P-glycoprotein substrates with a narrow therapeutic index should have their dose reduced and OATP1B1 substrates should be closely monitored for adverse effects if given concomitantly with Lupkyis. The most common adverse reactions (≥3%) reported with Lupkynis were decreased glomerular filtration rate, hypertension, diarrhea, headache, anemia, cough, urinary tract infection, abdominal pain upper, dyspepsia, alopecia, renal impairment, abdominal pain, mouth ulceration, fatigue, tremor, acute kidney injury, and decreased appetite.

New Drug Approvals, Continued

Verquvo (vericiguat)

Indication: Heart failure with reduced ejection fraction (HFrEF)

Mechanism of Action: Soluble guanylate cyclase stimulator

Dosage Form(s): Tablets

Comments: Verquvo is FDA-approved for treating adults with symptomatic, chronic HFrEF (<45%) to lower the risk for cardiovascular death and heart failure hospitalization after heart failure hospitalization or the need for outpatient IV diuretics. Verquvo is given as a starting dose of 2.5mg by mouth once daily with food, and the dose should be doubled every 2 weeks to a target maintenance dose of 10mg once daily. Verquvo carries a Boxed Warning for embryo-fetal toxicity, so pregnancy should be excluded prior to initiating, and females of reproductive potential should use effective forms of contraception throughout therapy and for one month after discontinuation. Blood pressure and complete blood count (CBC) should be monitored. Concomitant administration of Verquvo with other soluble guanylate cyclase stimulators is contraindicated. Additionally, concomitant administration with phosphodiesterase type 5 (PDE-5) inhibitors should be avoided in order to prevent the potential risk for hypotension. The most common adverse reactions (≥5%) reported with Verquvo were hypotension and anemia.

Vocabria (cabotegravir)

Indication: Human immunodeficiency virus type-1 (HIV-1)

Mechanism of Action: HIV-1 integrase strand transfer inhibitor (INSTI)

Dosage Form(s): Tablets

Comments: Vocabria is FDA-approved as short-term therapy, in combination with rilpivirine, for treating adults with HIV-1 infection on a stable antiretroviral regimen who are virologically suppressed (HIV-1 RNA <50 copies/mL) with no history of treatment failure or known or suspected resistance to Vocabria or rilpivirine. It is indicated to be used as oral lead-in to assess the tolerability of Vocabria prior to starting Cabenuva (cabotegravir; rilpivirine) or oral therapy for patients who will miss planned Cabenuva injections. Vocabria is given as 30mg orally once daily for one month in combination with rilpivirine 25mg orally once daily with food. Vocabria carries labeled warnings for hypersensitivity reactions, hepatotoxicity, depressive disorders, and risks associated with combination treatment. The following laboratory tests should be monitored throughout Vocabria therapy: blood glucose, CBC, CD4+ T cell count, hepatitis B serology, liver function tests, hepatitis C RNA, HIV-1 RNA, pregnancy testing, serum bilirubin, serum cholesterol, serum lipid profile, and urinalysis. Concomitant administration of Vocabria with any other antiretroviral drug besides rilpivirine for treating HIV-1 is not advisable. Additionally, uridine diphosphate glucuronosyltransferase (UGT)1A1 inducers may reduce the plasma concentrations of Vocabria. Concomitant administration of Vocabria with carbamazepine, oxcarbazepine, phenobarbital, phenytoin, rifampin, or rifapentine is contraindicated, and antacids with polyvalent cations should be administered 2 hours before or 4 hours after Vocabria. The most common adverse reactions (Grade 1-4) reported in ≤3 patients taking Vocabria were headache, nausea, abnormal dreams, anxiety, and insomnia.

Current Drug Shortages

The following shortages have been recently identified by the FDA:

- Calcium disodium versenate injection
- Dexmedetomidine injection
- Isoniazid injection USP

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
Cabenuva (Cabotegravir and rilpivirine)	HIV-1	HIV-1 INSTI and HIV-1 non-nucleoside reverse transcriptase inhibtor (NNRTI)	Extended-release injectable suspension	New combination, new dosage form

Creighton University Center for Drug Information & Evidence-Based Practice
Drug Information Consultation Service

Monday through Friday
7:30am-3:30pm Central
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