Generic Name:
Darunavir, cobicistat, emtricitabine, tenofovir alafenamide
Trade Name:
Symtuza
Company:
Janssen
Notes:

Janssen announced FDA approval of darunavir 800 mg, cobicistat 150 mg, emtricitabine 200 mg, and tenofovir alafenamide 10 mg under the trade name Symtuza?the first and only complete, darunavir-based single-tablet regimen (STR) for the treatment of HIV-1 in treatment-naive and certain virologically suppressed adults.

Symtuza combines the high barrier to resistance of darunavir with a formulation designed for improved tolerability and the convenience of an STR.

Approval was based on data from two 48-week, noninferiority, pivotal Phase III studies that assessed the safety and efficacy of Symtuza versus a control regimen in adults with no prior antiretroviral history (AMBER) and in virologically suppressed adults (EMERALD).

Results from both trials demonstrated that Symtuza was effective and well tolerated, with up to 95% achieving or maintaining virologic suppression (HIV-1 RNA < 50 c/mL).

The recommended dosage of Symtuza is one tablet taken once daily with food. Symtuza is not recommended in patients with creatinine clearance below 30 mL per minute or those with severe hepatic impairment.

According to the prescribing information, prior to or when initiating treatment with Symtuza, patients should be tested for hepatitis B virus (HBV) infection and renal function, and renal function should be monitored as clinically appropriate during therapy. The agent comes with a boxed warning on the risk of posttreatment acute exacerbation of hepatitis B.

Medication Monitor Categories:
Supplemental Approvals