SYMTUZA® (darunavir, cobicistat, emtricitabine, and tenofovir alafenamide) Safety Information of SYMTUZA - Lactic Acidosis or Severe Hepatomegaly with Steatosis

SUMMARY

- Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of nucleoside analogs, including emtricitabine (FTC), a component of SYMTUZA, and tenofovir disoproxil fumarate (TDF), another prodrug of tenofovir. Treatment with SYMTUZA should be suspended in any patient who develops clinical or laboratory findings suggestive of lactic acidosis or pronounced hepatotoxicity (which may include hepatomegaly and steatosis even in the absence or marked transaminase elevations).[1]
- There were no cases of lactic acidosis or severe hepatomegaly with steatosis reported in the phase 3 studies AMBER and EMERALD through 96 weeks.[2, 3]

DATA FROM PIVOTAL PHASE 3 CLINICAL TRIALS

HIV-1 Patients with No Prior Antiretroviral Treatment History

AMBER Study

The AMBER study was a phase 3, randomized, active-controlled, double-blind study to evaluate efficacy and safety of SYMTUZA vs darunavir (DRV)/cobicistat (COBI) fixed dose combination co-administered with FTC/TDF in antiretroviral treatment-naïve human immunodeficiency virus type 1 (HIV-1)-infected adults (N=725).[4, 5]

There were no reports of lactic acidosis/severe hepatomegaly with steatosis in the AMBER study through 96 weeks.[2]

HIV-1 Virologically-Suppressed Patients Who Switched to SYMTUZA

EMERALD Study

The EMERALD study was a phase 3, randomized, active-controlled, open-label study to evaluate the efficacy, safety, and tolerability of switching to SYMTUZA versus continuing the current regimen consisting of a boosted protease inhibitor (bPI) combined with FTC/TDF in virologically-suppressed, HIV-1-infected adults (N=1141).[6, 7]

There were no reports of lactic acidosis/severe hepatomegaly with steatosis in the EMERALD study through 96 weeks.[3]

LITERATURE SEARCH

A literature search of MEDLINE®, EMBASE®, BIOSIS Previews®, and DERWENT® (and/or other resources, including internal/external databases) pertaining to this topic was conducted on 07 July 2023.

REFERENCES

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4. Eron JJ, Orkin C, Gallant J, et al. A week-48 randomized phase-3 trial of darunavir/cobicistat/emtricitabine/tenofovir alafenamide in treatment-naive HIV-1 patients. *AIDS*. 32(11):1431-1442.

5. Orkin C, Eron J, Rockstroh J, et al. Week 96 results of a phase 3 trial of darunavir/cobicistat/emtricitabine/tenofovir alafenamide in treatment-naive HIV-1 patients. *AIDS*. 2020;34(5):707-718.

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