SYMTUZA® (darunavir, cobicistat, emtricitabine, and tenofovir alafenamide)
Safety Information of SYMTUZA– Sulfa Allergy

SUMMARY

- In the AMBER study, 1 (0.3%) patient in the control group who experienced 2 rash events had a history of sulfonamide allergy; the rash was due to a suspected Bactrim (sulfamethoxazole/trimethoprim) allergy.[1,2]
- There is no information regarding the number of patients with/without a sulfonamide allergy who received SYMTUZA in the EMERALD study or the DIAMOND study.[3,4]

DATA FROM PHASE 3 CLINICAL TRIALS

The data provided below are from phase 3 clinical studies for SYMTUZA.

HIV-1 Patients with No Prior Antiretroviral Treatment History

AMBER Study

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

Rash-associated adverse events were evaluated separately in patients with or without a history of sulfonamide allergy (Tables: Overview of Rash Events by History of Sulfonamide Allergy at Week 48 and Overview of Rash Events by History of Sulfonamide Allergy in the Initial SYMTUZA Group at Week 96).

Overview of Rash Events by History of Sulfonamide Allergy at Week 48[1]

	SYMTUZA		Control	
	Overall	Related	Overall	Related
Analysis set: intent-to-treat, N	362		363	
Rash Events/Patients with a History of Sulfonamide Allergy	0/6	0	1 (0.3%)/4	0
No History of Sulfonamide Allergy	47 (13.0%)	27 (7.5%)	38 (10.5%)	22 (6.1%)

Overview of Rash Events by History of Sulfonamide Allergy in the Initial SYMTUZA Group at Week 96[2]

	Week 48 – Week 96		Baseline – Week 96	
	Overall	Related	Overall	Related
Analysis set: intent-to-treat, N	335		362	
Rash Events/Patients with a History of Sulfonamide Allergy	0/6	0	0/6	0
No History of Sulfonamide Allergy	7 (2.1%)	0	52 (14.4%)	27 (7.5%)

DIAMOND Study

The DIAMOND study is a phase 3, single-arm, open-label, multicenter study to evaluate the safety and efficacy of SYMTUZA in newly diagnosed, HIV-1 infected, treatment-naïve patients in a rapid initiation model of care over 48 weeks (N=109).[3]

There is no information regarding the number of patients with/without a sulfonamide allergy who received SYMTUZA in the DIAMOND study.

HIV-1 Virologically-Suppressed Patients Who Switched to SYMTUZA

EMERALD Study

The EMERALD study is 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).[4]

There is no information regarding the number of patients with/without a sulfonamide allergy who received SYMTUZA in the EMERALD study.

LITERATURE SEARCH

A literature search of MEDLINE®, Embase®, BIOSIS Previews®, and Derwent Drug File (and/or other resources, including internal/external databases) pertaining to this topic was conducted on 27 February 2025.

REFERENCES

1. Data on File. 48 Week Clinical Study Report TMC114FD2HTX3001 (AMBER). Janssen Research & Development, LLC. EDMS-ERI-132892223; 2017.

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3. Huhn GD, Crofoot G, Ramgopal M, et al. Darunavir/cobicistat/emtricitabine/tenofovir alafenamide in a rapid-initiation model of care for human immunodeficiency virus type 1 infection: primary analysis of the DIAMOND study. Clin Infect Dis. 2020;71(12):3110-3117.

4. Orkin C, Molina JM, Negredo E, et al. Efficacy and safety of switching from boosted protease inhibitors plus emtricitabine and tenofovir disoproxil fumarate regimens to single-tablet darunavir, cobicistat, emtricitabine, and tenofovir alafenamide at 48 weeks in adults with virologically suppressed HIV-1 (EMERALD): a phase 3, randomised, non-inferiority trial. Lancet HIV. 2018;5(1):e23-e34.

5. 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. 2018;32(11):1431-1442.