

**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 48¹

	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 96²

	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[®] (and/or other resources, including internal/external databases) pertaining to this topic was conducted on 08 March 2023.

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 HIV-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.