PREZCOBIX® (darunavir/cobicistat)
PREZCOBIX - Safety Information - Sulfa Allergy

SUMMARY

- There is no information regarding the number of patients with/without a sulfonamide allergy who received darunavir (DRV) and cobicistat (COBI) administered as single agents in the GS-US-216-0130 study.[1]
- In the AMBER study, which compared PREZCOBIX + emtricitabine/tenofovir disoproxil fumarate (FTC/TDF) with the single-tablet regimen (STR) DRV/COBI/FTC/tenofovir alafenamide (TAF), 1 (0.3%) patient in the PREZCOBIX group who experienced 2 rash events had a history of sulfonamide allergy.[2-4]

DATA FROM STUDIES WITH DRV/COBI

GS-US-216-0130 Study

GS-US-216-0130 is a phase 3b, open-label, single arm, 48 week, multicenter US study evaluating the safety, tolerability, efficacy, and pharmacokinetics of DRV 800 mg + COBI 150 mg once daily (QD; administered as single agents) in combination with 2 fully active nucleoside reverse transcriptase inhibitors (NRTIs) in treatment-naïve and treatment-experienced (no DRV resistance-associated mutations [RAMs]) HIV-1-infected patients (N=313; n=295 treatment-naïve).[1]

- There is no information regarding the number of patients with/without a sulfonamide allergy who received DRV and COBI in the GS-US-216-0130 study.

DATA FROM STUDIES WITH DRV/COBI/FTC/TAF STR

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 the STR DRV/COBI/FTC/TAF vs the fixed-dose combination PREZCOBIX co-administered with FTC/TDF in treatment-naïve HIV-1-infected adults (N=725). At week 48, patients in the PREZCOBIX group switched to the STR and data were collected until week 96.[2]

Rash-associated adverse events were evaluated separately in patients with or without a history of sulfonamide allergy. Through week 48, one (0.3%) patient in the PREZCOBIX group who experienced rash events (rash macular and drug eruption) had a history of sulfonamide allergy (Table: Overview of Rash Events by History of Sulfonamide Allergy at Week 48.[3]

Overview of Rash Events by History of Sulfonamide Allergy at Week 48[3]

	DRV/COBI/FTC/TAF		PREZCOBIX + FTC/TDF	
	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%)
Abbreviations: COBI, cobicistat; DRV, darunavir; FTC, emtricitabine; TAF, tenofovir alafenamide; TDF, tenofovir disoproxil fumarate.				

- Between weeks 48 and 96, there were 7 additional rash events in the initial STR group and 6 in the PREZCOBIX + FTC/TDF group following switch to the STR; none occurred in patients with a history of sulfonamide allergy.[4]

LITERATURE SEARCH

A literature search of MEDLINE®, EMBASE®, BIOSIS Previews®, and DERWENT® databases (and/or other resources, including internal/external databases) pertaining to this topic was conducted on 17 April 2023.

REFERENCES

1. Tashima K, Crofoot G, Tomaka FL, et al. Cobicistat-boosted darunavir in HIV-1-infected adults: week 48 results of a phase IIIb, open-label single-arm trial. *AIDS Res Ther*. 2014;11:39.
2. 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.
3. Data on File. 48 Week Clinical Study Report TMC114FD2HTX3001 (AMBER). Janssen Research & Development, LLC. EDMS-ERI-132892223; 2017.
4. Data on File. 96 Week Clinical Study Report TMC114FD2HTX3001 (AMBER). Janssen Research & Development, LLC. EDMS-ERI-163159317; 2018.