

# Darunavir-Cobicistat (*Prezcobix*)

## Table of Contents

- [Darunavir-Cobicistat \*Prezcobix\* Editor's Summary](#)
- [Drug Summary](#)
- [Guidelines for use in Antiretroviral-Naïve Patients](#)
- [Key Clinical Trials](#)
- [Adverse Effects](#)
- [Use In Pregnancy](#)
- [Resistance](#)
- [Key Drug Interactions](#)

## Drug Summary

Darunavir-cobicistat is a fixed-dose combination pill consisting of a protease inhibitor (darunavir) and a pharmacologic booster (cobicistat). Fixed-dose darunavir-cobicistat is an option for initial antiretroviral therapy and as a component of salvage regimens for treatment-experienced individuals if once-daily dosing is indicated (note that darunavir-cobicistat is approved only for once daily dosing). Available data suggest once-daily darunavir-cobicistat and once-daily darunavir plus ritonavir are equivalent and tolerability is similar. As an anchor drug, darunavir-cobicistat has high potency and a high barrier to drug resistance, but also several downsides that include gastrointestinal side effects and drug interactions. Darunavir has a sulfonamide moiety so this combination should be used with caution for individuals with known sulfonamide allergy.

---

## Guidelines for use in Antiretroviral-Naïve Patients

In the July 14, 2016 version of the HHS Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents, **darunavir-cobicistat** is classified as listed below for treatment-naïve patients:

### RECOMMENDED Regimen Options:

- Not listed

### ALTERNATIVE Regimen Options:

- **Darunavir-cobicistat** plus abacavir-lamivudine—only if HLA-B\*5701 negative (**BIII**)
- **Darunavir-cobicistat** plus tenofovir DF-emtricitabine (**BII**)
- **Darunavir-cobicistat** plus tenofovir alafenamide-emtricitabine (**BII**)

---

## Key Clinical Trials

No studies have directly compared darunavir-cobicistat with darunavir plus ritonavir. An open-label, phase 3b, single-arm study enrolled treatment-naïve adults and a small number of treatment-experienced adults (all with HIV RNA above 1,000 copies/mL and with no darunavir-associated mutations) and administered once-daily darunavir plus cobicistat (as separate pills) plus an optimized background regimen to all participants; results demonstrated overall high efficacy (81% with HIV RNA less than 50 copies/mL) and tolerability through 48 weeks [[GS-216-0130 \(Study 130\)](#)]. Another noncomparative trial enrolled individuals with suppressed HIV RNA and creatinine clearance 50 to 89 mL/min while taking a regimen that included ritonavir-boosted darunavir or ritonavir-boosted atazanavir; all participants switched from ritonavir to cobicistat and 89% remained virologically suppressed at 96 weeks [[GS-236-0118 \(Study 118\)](#)]. Mild, nonprogressive increases in serum creatinine were noted early after the switch (as expected secondary to cobicistat) but no cases of renal proximal tubulopathy developed.

---

## Adverse Effects

Common adverse effects with darunavir-cobicistat are nausea, diarrhea, and other gastrointestinal symptoms. Darunavir may also cause headache, rash, elevation of hepatic aminotransferase levels, and worsening of serum lipid levels. Darunavir contains a sulfonamide moiety and thus should be used cautiously in individuals with a history of sulfonamide allergy. Although the rates of allergic reaction with darunavir are higher in individuals with history of sulfonamide allergy when compared with individuals with no history of sulfonamide allergy, clinically significant reactions infrequently occur. Nonetheless, most experts would avoid use of darunavir in patients with a history of severe sulfonamide allergy, such as a prior incidence of Stevens-Johnson syndrome. Cobicistat blocks tubular secretion of creatinine and thereby causes a mild benign elevation of serum creatinine and reduction of estimated GFR (with no effect on true or measured GFR).

---

## Use In Pregnancy

In the October 26, 2016 version of the HHS Perinatal Guidelines, **darunavir-cobicistat** is designated in the category of Insufficient Data in Pregnancy to Recommend Routine Use in Initial Regimens for Antiretroviral-Naïve Women. This recommendation is based on the limited data on cobicistat and darunavir-cobicistat in pregnancy.

- For additional information regarding the safety and toxicity of darunavir-cobicistat in pregnancy see the HHS Perinatal Guidelines summaries on [Darunavir](#) and [Cobicistat](#).

---

## Resistance

For a listing of the most common clinically significant mutations associated with darunavir-cobicistat (DRV-COBI) resistance, see the [PI Resistance Notes on the Stanford University HIV Drug Resistance Database](#).

---

## Key Drug Interactions

For complete information on darunavir-cobicistat-related drug interactions, see the [Drug Interactions section in the Darunavir-Cobicistat \(Prezcobix\) Prescribing Information](#).

---

## No Clinical Trials Available

We do not currently have any clinical trials on file for this drug.