Cobicistat (COBI)

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Formulations

Fixed-Dose Combination (FDC) Tablets

- [Evotaz] Atazanavir 300 mg/cobicistat 150 mg
- [Genvoya] Elvitegravir 150 mg/cobicistat 150 mg/emtricitabine 200 mg/tenofovir alafenamide 10 mg
- [Prezcobix] Darunavir 800 mg/cobicistat 150 mg (pediatric dose for children ≥40 kg)
- [Prezcobix] Darunavir 675 mg/cobicistat 150 mg (pediatric dose for children 25 kg to 40 kg)
- [Prezcobix PED] Darunavir 600-mg/cobicistat 90-mg dispersible tablet (pediatric dose for children weighing ≥15 kg to <25 kg)
- [Stribild] Elvitegravir 150 mg/cobicistat 150 mg/emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg
- [Symtuza] Darunavir 800 mg/cobicistat 150 mg/emtricitabine 200 mg/ tenofovir alafenamide 10 mg

When using FDC tablets, refer to other sections of Appendix A. Pediatric Antiretroviral Drug Information for information about the individual components of the FDC. See also Appendix A, Table 2. Antiretroviral Fixed-Dose Combination Tablets and Co-packaged Formulations: Minimum Body Weights and Considerations for Use in Children and Adolescents.

For additional information, see Drugs@FDA or DailyMed.

Dosing Recommendations

Cobicistat (COBI) Is a Pharmacokinetic (PK) Enhancer

- The only use of COBI is as a PK enhancer (boosting agent) for certain protease inhibitors (PIs) and integrase strand transfer inhibitors. COBI **is not interchangeable** with ritonavir (RTV) and has no antiviral activity.

Note: DRV use is restricted to children age ≥3 years.

Child (Weighing ≥15 kg to <25 kg)

- COBI 90-mg/darunavir (DRV) 600-mg FDC dispersible tablet

Child and Adolescent (Weighing ≥25 kg to <40 kg)

- COBI 150-mg/DRV 675-mg FDC tablet

Child and Adolescent (Weighing ≥35 kg) and Adult Dose

- COBI 150 mg coformulated with atazanavir (ATV) 300 mg administered at the same time with food

Selected Adverse Events

- COBI is an inhibitor of renal tubular transporters of creatinine. This increases serum creatinine and reduces the estimated glomerular filtration rate, with no change in glomerular function.

Special Instructions

- COBI 150 mg **is not interchangeable** with RTV, but it has a PK-boosting effect that is comparable to RTV 100 mg.
- Drug interactions may differ between RTV and COBI because COBI is a stronger P-glycoprotein inhibitor and lacks some of the induction effects of RTV.
- **Do not administer** COBI with RTV or with FDC tablets that contain COBI.
- COBI **is not recommended** for use with more than one ARV drug that requires PK enhancement (e.g., EVG used in combination with a PI).
- Using COBI with PIs other than once-daily ATV or DRV **is not recommended.**

Child and Adolescent (Weighing ≥40 kg) and Adult Dose

- COBI 150 mg with DRV 800 mg administered at the same time with food

[Evotaz] ATV/COBI

Child and Adolescent (Weighing ≥35 kg) and Adult Dose

- One tablet once daily with food
- Use in combination with other antiretroviral (ARV) drugs.

[Genvoya] Elvitegravir (EVG)/COBI/ Emtricitabine (FTC)/Tenofovir Alafenamide (TAF)

Child (Weighing ≥14 kg to <25 kg)

- Limited data currently exist on the appropriate dose of Genvoya in children weighing ≥14 kg to <25 kg. Studies assessing the safety and efficacy of a low-dose tablet with EVG 90 mg/COBI 90 mg/ FTC 120 mg/TAF 6 mg found that it resulted in maintenance of viral suppression but lower median observed EVG trough concentrations than in adults. (See the Elvitegravir section).

Child and Adolescent (Weighing ≥25 kg) and Adult Dose

- One tablet once daily with food

[Prezcobix] DRV/COBI

Child (Aged ≥3 Years and Weighing ≥15 kg to <25 kg)

- DRV 600 mg/COBI 90 mg (Prezcobix PED)
- One tablet for oral suspension taken once daily with food.

Child and Adolescent (Weighing ≥25 kg and ≤40 kg)

- DRV 675 mg/COBI 150 mg
- One tablet once daily with food
- Use in combination with other ARV drugs

Child and Adolescent (Weighing ≥40 kg) and Adult Dose

- DRV 800 mg/COBI 150 mg
- One tablet once daily with food
- Use in combination with other ARV drugs.

[Stribild] EVG/COBI/FTC/Tenofovir Disoproxil Fumarate (TDF)

Child and Adolescent (Weighing ≥35 kg) and Adult Dose

- One tablet once daily with food

- Patients with a confirmed increase in serum creatinine >0.4 mg/dL from baseline should be closely monitored for renal safety.
- When using COBI in combination with TDF, monitor serum creatinine, urine protein, and urine glucose at baseline and every 3 to 6 months while the patient is receiving therapy (see Table 17i. Nephrotoxic Effects). In patients who are at risk of renal impairment, serum phosphate also should be monitored.
- For information on crushing and cutting tablets, see Information on Crushing and Liquid Drug Formulations from Toronto General Hospital.

Metabolism/Elimination

- COBI is a strong inhibitor of cytochrome P450 (CYP) 3A4 and a weak inhibitor of CYP2D6.

COBI Dosing in Patients With Hepatic Impairment

- COBI does not require dose adjustment in patients with mild-to-moderate hepatic impairment. No data are available in patients with severe hepatic impairment. Dosing recommendations for medications that are coadministered with COBI should be followed.
- Genvoya, Prezcobix, Stribild, and Symtuza **are not recommended** in patients with severe hepatic impairment.
- Evotaz **is not recommended** in patients with any degree of hepatic impairment.

COBI Dosing in Patients With Renal Impairment

- COBI does not require a dose adjustment in patients with renal impairment, including those with severe renal impairment. Dosing recommendations for medications that are coadministered with COBI should be followed.
- The use of COBI plus TDF **is not recommended** in patients with creatinine clearance (CrCl) <70 mL/min. Dose adjustments for TDF are required for patients with CrCl <50 mL/min, and the necessary dose adjustments for TDF when this drug is used with COBI have not been established in this group of patients.
- Genvoya **is not recommended** in patients with estimated CrCl 15 to <30 mL/min, or in patients with estimated CrCl <15 mL/min who are not receiving chronic hemodialysis.

• The Panel on Antiretroviral Therapy and Medical Management of Children Living With HIV recommends using Stribild only in patients with sexual maturity ratings of 4 or 5. **[Symtuza] DRV/COBI/FTC/TAF** *Child and Adolescent (Weighing ≥40 kg) and Adult Dose* • One tablet once daily with food	• Stribild **should not be initiated** in patients with estimated CrCl <70 mL/min and should be discontinued in patients with estimated CrCl <50 mL/min. The dose adjustments required for FTC and TDF in these patients cannot be achieved with an FDC tablet. • Symtuza **is not recommended** in patients with estimated CrCl <30 mL/min.

Drug Interactions

Additional information about drug interactions is available in the Liverpool HIV Drug Interaction Checker.

- *Metabolism:* Metabolism of cobicistat (COBI) is mainly via cytochrome P450 (CYP) 3A4 and, to a lesser degree, CYP2D6. COBI is a strong inhibitor of CYP3A4 and a weak inhibitor of CYP2D6. COBI also inhibits breast cancer resistance protein, P-glycoprotein (P-gp), the organic anion transporting polypeptides organic anion transporting polypeptide (OATP) 1B1 and OATP1B3, and multidrug and toxin extrusion 1. Unlike ritonavir, COBI does not demonstrate any enzyme-inducing effects. The potential exists for multiple drug interactions when using COBI. Before COBI is administered, a patient's medication profile should be carefully reviewed for potential interactions and overlapping toxicities with other drugs. Coadministration of medications that induce or inhibit CYP3A4 may respectively decrease or increase exposures of COBI and coformulated antiretroviral (ARV) medications. Coadministration of medications that are CYP3A4 substrates may result in clinically significant adverse reactions that are severe, life-threatening, or fatal, or may result in loss of therapeutic effect if dependent on conversion to an active metabolite due to CYP3A4 inhibition by COBI.[1]
- *Nucleoside reverse transcriptase inhibitors:* COBI is a strong P-gp inhibitor; thus, a dose of tenofovir alafenamide (TAF) 10 mg combined with COBI produces tenofovir (TFV) exposures that are similar to those produced by TAF 25 mg without COBI.[2] COBI increases plasma TFV exposures by 23% when it is coadministered with TDF; thus, renal safety should be monitored in patients who are receiving this combination.[1,3]
- *Non-nucleoside reverse transcriptase inhibitors:* Efavirenz, etravirine, and nevirapine **should not be used** with COBI.
- *Protease inhibitors:* Using COBI as a dual booster for elvitegravir (EVG) and darunavir (DRV) has been studied in people with and without HIV, and the evidence is conflicting. When EVG plus COBI plus DRV was administered to people without HIV, the trough concentration (C_{trough}) of EVG was 50% lower than the C_{trough} seen in people who received elvitegravir/cobicistat (EVG/c)/emtricitabine (FTC)/tenofovir disoproxil fumarate (TDF) without DRV.[4] When EVG/c/FTC/TAF was administered with DRV to patients with HIV, both DRV and EVG concentrations were comparable to those seen in historic controls.[5,6]
- *Integrase inhibitors:* In one small study, dolutegravir (DTG) C_{trough} was 107% higher when DTG was administered with darunavir/cobicistat (DRV/c) than when it was administered with darunavir/ritonavir.[7] Bictegravir (BIC) area under the curve increases 74% when BIC is administered with DRV/c.[8]
- *Corticosteroids:* Increased serum concentrations of corticosteroids can occur when corticosteroids and COBI are coadministered; this can lead to clinically significant adrenal suppression. Adrenal suppression occurs regardless of whether the corticosteroids are administered orally or by some other route (e.g., intranasal, inhaled, interlaminar, intraarticular)

and regardless of whether the corticosteroids are administered routinely or intermittently. A possible exception is beclomethasone, which appears to be a relatively safe option with inhaled or intranasal administration.[9,10]

Major Toxicities

- *More common:* Nausea, vomiting, diarrhea, abdominal pain, anorexia
- *Less common (more severe):* New onset renal impairment or worsening of renal impairment when used with TAF or TDF, rhabdomyolysis, increased amylase and lipase levels
- *Case Report:* One case report exists of a woman with low body weight (36 kg) and declining renal function who developed severe Type B lactic acidosis while on the combination of COBI, DRV, and non–dose-adjusted TDF/FTC. The woman's TFV C_{trough} during this episode was found to be up to fivefold higher than trough values reported in adults with normal renal function. The woman's FTC concentration was not measured.[11]

Resistance

Not applicable because COBI has no antiviral activity.

Pediatric Use

Approval

COBI is a pharmacokinetic (PK) enhancer of ARV drugs that is available as a single agent or a component of fixed-dose combination products. COBI, as a component of Stribild, is approved by the U.S. Food and Drug Administration (FDA) at the adult dose for use in children and adolescents aged ≥12 years and weighing ≥35 kg.[12] The Panel on Antiretroviral Therapy and Medical Management of Children Living With HIV recommends limiting the use of Stribild to those with a sexual maturity rating of 4 or 5. COBI, as a component of Genvoya, is approved by the FDA at the adult dose for use in children weighing ≥25 kg.[13] The FDA has not approved COBI as a component of Genvoya for use in children weighing <25 kg, but a PK, safety, and efficacy study has been conducted with a low-dose tablet in children weighing ≥14 kg to <25 kg (see the Elvitegravir section). COBI alone (as Tybost) has been discontinued, and no generic standalone tablet formulation of COBI exists.[1] Prezcobix PED dispersible tablets are available for HIV treatment in children aged ≥3 years and weighing ≥15 kg.[15] COBI, coformulated with ATV (as Evotaz),[14] is approved by the FDA at the adult dose for use in children and adolescents weighing ≥35 kg. COBI, coformulated with DRV (as Prezcobix)[15] and as a component of Symtuza,[16] is approved by the FDA in children and adolescents weighing ≥25 kg. COBI, as a component of Symtuza, is approved by the FDA at the adult dose in children and adolescents weighing ≥40 kg.

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