# HIV STR Medicine Options*

Symtuza®
darunavir/cobicistat/emtricitabine/tenofovir alafenamide tablets
800mg/150mg/200mg/10mg

**There are different types of medicines to treat HIV-1 (Human Immunodeficiency Virus). These medicines are co-formulated, single-tablet regimens (STRs).**


**SYMTUZA®**
darunavir/cobicistat/emtricitabine/tenofovir alafenamide (DRV/c/FTC/TAF)


**Atripla®**
efavirenz/emtricitabine/tenofovir disoproxil fumarate (EFV/FTC/TDF)


**Complera®**
rilpivirine/emtricitabine/tenofovir disoproxil fumarate (RPV/FTC/TDF)


**Stribild®**
elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil fumarate (EVG/c/FTC/TDF)


**Odefsey®**
rilpivirine/emtricitabine/tenofovir alafenamide (RPV/FTC/TAF)


**Genvoya®**
elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide (EVG/c/FTC/TAF)


**Triumeq®**
dolutegravir/abacavir/lamivudine (DTG/ABC/3TC)


**Juluca®**
dolutegravir/rilpivirine (DTG/RPV)


**Biktarvy®**
bictegravir/emtricitabine/tenofovir alafenamide (BIC/FTC/TAF)


**Delstrigo™**
doravirine/tenofovir disoproxil fumarate/lamivudine (DOR/TDF/3TC)


**Dovato™**
dolutegravir/lamivudine (DTG/3TC)

## IMPORTANT SAFETY INFORMATION

### BOXED WARNING: POST TREATMENT ACUTE EXACERBATION OF HEPATITIS B

- **Severe acute exacerbations of hepatitis B (HBV) have been reported in patients who are coinfected with HIV-1 and HBV and have discontinued products containing emtricitabine and/or tenofovir disoproxil fumarate (TDF) and may occur with discontinuation of SYMTUZA®.**

  **Action:** Monitor hepatic function with both clinical and laboratory follow-up for at least several months in patients who are coinfected with HIV-1 and HBV and discontinue SYMTUZA®. If appropriate, anti-hepatitis B therapy may be warranted.

**Please see Important Safety Information throughout and attached full Prescribing Information, including Boxed WARNING for SYMTUZA®.**

Pills are shown at approximate size.
This chart does not include all HIV treatment formulations, treatment options, or dosing or safety considerations for the use of antiretroviral agents.
*Indications, safety, and efficacy of these products may vary. Please refer to the full Prescribing Information or Patient Information of each medication for more details.

## INDICATION

SYMTUZA® is indicated as a complete regimen for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults:

- who have no prior antiretroviral treatment history or
- who are virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen for at least 6 months and have no known substitutions associated with resistance to darunavir or tenofovir.

## IMPORTANT SAFETY INFORMATION (Cont'd)

## CONTRAINDICATIONS

- Do not coadminister SYMTUZA® and the following drugs due to the potential for serious and/or life-threatening events or loss of therapeutic effect: alfuzosin, carbamazepine, cisapride, colchicine (in patients with renal and/or hepatic impairment), dronedarone, elbasvir/grazoprevir, ergot derivatives (such as: dihydroergotamine, ergotamine, methylergonovine), ivabradine, lomitapide, lovastatin, lurasidone, oral midazolam, naloxegol, phenobarbital, phenytoin, pimozide, ranolazine, rifampin, St. John's wort (***Hypericum perforatum***), sildenafil for pulmonary arterial hypertension, simvastatin, and triazolam.

## WARNINGS AND PRECAUTIONS

- **Hepatotoxicity:** Drug-induced hepatitis (e.g., acute hepatitis, cytolytic hepatitis) and cases of liver injury, including some fatalities, have been reported in patients receiving darunavir, a component of SYMTUZA®. Patients with pre-existing liver dysfunction, including chronic active hepatitis B or C, have an increased risk for liver function abnormalities, including severe hepatic adverse reactions.

  **Action:** Monitor liver function prior to initiating and during therapy, especially in patients with underlying chronic hepatitis, cirrhosis, or in patients who have pretreatment elevations of transaminases. Patients with evidence of new or worsening liver function should consider discontinuing SYMTUZA®. SYMTUZA® is not recommended in patients with severe hepatic impairment (Child-Pugh Class C).

- **Severe Skin Reactions:** In patients receiving darunavir, a component of SYMTUZA®, severe skin reactions may occur, including Stevens-Johnson syndrome, toxic epidermal necrolysis, drug rash with eosinophilia and systemic symptoms (DRESS), and acute generalized exanthematous pustulosis. These include conditions accompanied by fever and/or elevations of transaminases.

  **Action:** Discontinue SYMTUZA® immediately if signs or symptoms of severe skin reactions develop. These can include but are not limited to severe rash or rash accompanied with fever, general malaise, fatigue, muscle or joint aches, blisters, oral lesions, conjunctivitis, hepatitis, and/or eosinophilia.

- **Risk of Serious Adverse Reactions or Loss of Virologic Response Due to Drug Interactions:** Consult the full Prescribing Information prior to and during treatment for potential drug interactions.

- **Immune Reconstitution Syndrome:** Patients receiving SYMTUZA® may develop new onset or exacerbations of immune reconstitution syndrome.

- **New Onset or Worsening Renal Impairment:** Renal impairment, including cases of acute renal failure and Fanconi syndrome, has been reported with the use of tenofovir prodrugs. In clinical trials of SYMTUZA®, there were no cases of proximal renal tubulopathy, including Fanconi syndrome, reported in the SYMTUZA® group through Week 48. SYMTUZA® is not recommended in patients with creatinine clearance below 30 mL per minute. Patients taking tenofovir prodrugs who have impaired renal function and those taking nephrotoxic agents including nonsteroidal anti-inflammatory drugs are at increased risk of developing renal-related adverse reactions.

  **Action:** Prior to initiating or during treatment, on a clinically appropriate schedule, monitor serum creatinine, estimated creatinine clearance, urine glucose, and urine protein in all patients. In patients with chronic kidney disease, also assess serum phosphorus. Discontinue SYMTUZA® in patients who develop clinically significant decreases in renal function or evidence of Fanconi syndrome. Patients who experience a confirmed increase in serum creatinine of greater than 0.4 mg/dL should be closely monitored for renal safety.

- **Sulfa Allergy:** Darunavir contains a sulfonamide moiety. The incidence and severity of rash were similar in subjects with or without a history of sulfonamide allergy.

  **Action:** Monitor patients with a known sulfonamide allergy.

- **Lactic Acidosis/Severe Hepatomegaly With Steatosis:** Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of nucleoside analogs, including emtricitabine, a component of SYMTUZA®, and tenofovir disoproxil fumarate (TDF), another prodrug of tenofovir, alone or in combination with other antiretrovirals.

  **Action:** Discontinue SYMTUZA® in any patient who develops clinical or laboratory findings suggestive of lactic acidosis or pronounced hepatotoxicity.

- **Diabetes Mellitus/Hyperglycemia:** New-onset or exacerbations of pre-existing diabetes mellitus and hyperglycemia have been reported in patients receiving protease inhibitors.

  **Action:** Initiation or dose adjustments of insulin or oral hypoglycemic agents may be required.

- **Fat Redistribution:** Redistribution and/or accumulation of body fat have been observed in patients receiving antiretroviral therapy.

- **Hemophilia:** Patients with hemophilia may develop an increase in bleeding events.

## ADVERSE REACTIONS

- The most common clinical adverse reactions (all grades) occurring in at least 2% of treatment-naïve patients were diarrhea, rash,* nausea, fatigue, headache, abdominal discomfort, and flatulence.

*Includes pooled reported terms: dermatitis, dermatitis allergic, erythema, photosensitivity reaction, rash, rash generalized, rash macular, rash maculopapular, rash morbilliform, rash pruritic, toxic skin eruption, and urticaria.

Grade 2-4 laboratory abnormalities have been reported in patients receiving SYMTUZA®, including elevations in serum creatinine, liver function tests, triglycerides, total cholesterol, low-density lipoproteins, and glucose levels.

This is not a complete list of all adverse reactions reported with the use of SYMTUZA®. Please refer to the full Prescribing Information for a complete list of adverse drug reactions.

## USE IN SPECIFIC POPULATIONS

- **Pregnancy:** SYMTUZA® is not recommended for use during pregnancy and should not be initiated in pregnant individuals because of substantially lower exposures of darunavir and cobicistat during pregnancy.

  **Lactation:** The Centers for Disease Control and Prevention recommends that HIV-infected mothers in the United States not breastfeed their infants to avoid risking postnatal transmission of HIV-1 infection.

- Consult the full Prescribing Information for SYMTUZA® for additional information on the Uses in Specific Populations.

cp-62076v4

**Please see attached full Prescribing Information, including Boxed WARNING for SYMTUZA®.**

Symtuza®

darunavir/cobicistat/emtricitabine/
tenofovir alafenamide tablets
800mg/150mg/200mg/10mg

Janssen Therapeutics, Division of Janssen Products, LP

 07/19 cp-60024v5

Janssen Infectious Diseases

PHARMACEUTICAL COMPANIES OF Johnson & Johnson