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)

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™. Closely 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), lovastatin, lurasidone, oral midazolam, phenobarbital, phenytoin, pimozide, ranolazine, rifampin, St. John's wort (*Hypericum perforatum*), sildenafil for pulmonary arterial hypertension, simvastatin, and triazolam.

WARNINGS AND PRECAUTIONS

- **Severe Acute Exacerbation of Hepatitis B in Patients Coinfected With HIV-1 and HBV:** Patients with HIV-1 should be tested for the presence of chronic HBV before initiating antiretroviral therapy. Severe acute exacerbations of hepatitis B (e.g., liver decompensation and liver failure) have been reported in patients who are coinfected with HIV-1 and HBV and have discontinued products containing emtricitabine and/or tenofovir disoproxil fumarate, and may occur with discontinuation of SYMTUZA™.

  Patients coinfected with HIV-1 and HBV who discontinue SYMTUZA™ should be closely monitored with both clinical and laboratory follow-up for at least several months after stopping treatment. If appropriate, anti-hepatitis B therapy may be warranted, especially in patients with advanced liver disease

- **Immune Reconstitution Syndrome**, including the occurrence of autoimmune disorders with variable time to onset, had been reported in patients treated with combination antiretroviral therapy.

- **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. 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.

  In all patients, monitor serum creatinine, creatinine clearance, urine glucose, and urine protein prior to or when initiating SYMTUZA™ and during therapy. 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.

- **Sulfa Allergy:** Monitor patients with a known sulfonamide allergy after initiating SYMTUZA™.

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

or cirrhosis, since post-treatment exacerbation of hepatitis may lead to hepatic decompensation and liver failure.

- **Hepatotoxicity:** Drug-induced 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.

  Appropriate laboratory testing should be conducted prior to initiating and during therapy with SYMTUZA™. Evidence of new or worsening liver dysfunction (including clinically significant elevation of liver enzymes and/or symptoms such as fatigue, anorexia, nausea, jaundice, dark urine, liver tenderness, and hepatomegaly) should prompt consideration of interruption or discontinuation of SYMTUZA™.

- **Severe Skin Reactions:** In patients receiving darunavir, a component of SYMTUZA™, severe skin reactions may occur. Stevens-Johnson syndrome was reported with darunavir coadministered with cobicistat in clinical trials at a rate of 0.1%. During darunavir postmarketing experience, toxic epidermal necrolysis, drug rash with eosinophilia and systemic symptoms (DRESS), and acute generalized exanthematous pustulosis have been reported.

  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:** The concomitant use of SYMTUZA™ and other drugs may result in known or potentially significant drug interactions, some of which may lead to the loss of therapeutic effect of SYMTUZA™ and possible development of resistance or possible clinically significant adverse reactions from greater exposures of concomitant drugs.

  Consult the full Prescribing Information for potential drug interactions prior to and during SYMTUZA™ therapy, review concomitant medications during SYMTUZA™ therapy, and monitor for the adverse reactions associated with concomitant medications.

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

- **Hemophilia:** Increased bleeding in hemophiliacs has been reported in patients receiving protease inhibitors.

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

DRUG INTERACTIONS

- Consult the full Prescribing Information for SYMTUZA™ for information on significant drug interactions, including clinical comments.

USE IN SPECIFIC POPULATIONS

- **Pregnancy:** SYMTUZA™ is not recommended for use during pregnancy because of substantially lower exposures of darunavir and cobicistat during pregnancy.

  SYMTUZA™ should not be initiated in pregnant individuals. An alternative regimen is recommended for individuals who become pregnant during therapy with SYMTUZA™.

- **Renal Impairment:** SYMTUZA™ is not recommended in patients with severe renal impairment (creatinine clearance below 30 mL per minute).

- **Hepatic Impairment:** SYMTUZA™ is not recommended for use in patients with severe hepatic impairment (Child-Pugh Class C).

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

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

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Janssen Therapeutics, Division of Janssen Products, LP

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Janssen Infectious Diseases

PHARMACEUTICAL COMPANIES OF Johnson & Johnson