*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 additional Important Safety Information on the following page and full Prescribing Information, including Boxed WARNING for SYMTUZA®

Pills shown are not their actual 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 and pediatric patients weighing at least 40 kg:

- 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

- Darunavir and cobicistat are both inhibitors and substrates of the cytochrome P450 3A (CYP3A) isoform. SYMTUZA® should not be co-administered with medicinal products that are highly dependent on CYP3A for clearance and for which increased plasma concentrations are associated with serious and/or life-threatening events. In addition, co-administration of SYMTUZA® with CYP3A inducers is expected to lower plasma concentrations of darunavir and cobicistat which may lead to loss of efficacy of darunavir and development of resistance.

  Action: Examples of drugs that are contraindicated for co-administration with SYMTUZA® due to the potential for serious and/or life-threatening events or loss of therapeutic effect are listed below: alfuzosin, carbamazepine, 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:** Postmarketing cases of renal impairment, including acute renal failure, proximal renal tubulopathy (PRT), and Fanconi syndrome have been reported with tenofovir alafenamide (TAF)-containing products; while most of these cases were characterized by potential confounders that may have contributed to the reported renal events, it is also possible these factors may have predisposed patients to tenofovir-related adverse events. SYMTUZA® is not recommended in patients with estimated 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 must not breastfeed their infants to avoid risking postnatal transmission of HIV-1 infection.

- **Pediatric Use:** The safety and effectiveness of SYMTUZA® have not been established and is not recommended in pediatric patients weighing less than 40 kg.

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

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Janssen Therapeutics, Division of Janssen Products, LP

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Janssen Infectious Diseases & Vaccines
PHARMACEUTICAL COMPANIES OF Johnson & Johnson