



Syntuza

WHAT IS SYMTUZA?

Syntuza is a complete HIV regimen used as part of [antiretroviral therapy \(ART\)](#). Syntuza contains four [antiretroviral drugs \(ARVs\)](#) combined in one tablet:

- [darunavir \(DRV, Prezista\)](#)
- [cobicistat \(COBI, Tybost\)](#)
- [emtricitabine \(FTC, Emtriva\)](#)
- tenofovir alafenamide fumarate (tenofovir AF, TAF, Vemlidy)

The FDA approved Syntuza in 2018 as an ARV for people with HIV infection. Syntuza is manufactured by [Janssen Therapeutics](#).

One of the drugs in Syntuza, darunavir, is a type of drug called a [protease inhibitor \(PI\)](#). PIs block protease (an HIV enzyme). By blocking protease, PIs prevent new (immature) HIV from becoming a mature virus that can infect other CD4 cells. One of the drugs in Syntuza, cobicistat, is a type of drug called a [pharmacokinetic enhancer \(PK enhancer\)](#) or CYP3A inhibitor. PK enhancers are used to boost the effectiveness of other drugs. When the two drugs are given together, the PK enhancer interferes with the liver metabolism and breakdown of the other drug, which allows the other drug to remain in the body longer at a higher concentration. PK enhancers are included in some HIV treatment regimens. Cobicistat itself is not an ARV and does not treat HIV. The final two drugs in Syntuza, emtricitabine and tenofovir AF, are [nucleoside reverse transcriptase inhibitors \(NRTIs\)](#). NRTIs bind to and block reverse transcriptase (an HIV enzyme). HIV uses reverse transcriptase to convert its RNA into DNA (reverse transcription). Blocking reverse transcriptase and reverse transcription prevents HIV from replicating.

When used alone as a complete regimen to treat HIV infection, Syntuza may help:

- Reduce the amount of HIV in your blood. This is called [viral load](#).
- Increase the number of [CD4 cells](#) in your blood that help fight off other infections.

Reducing the amount of HIV and increasing CD4 cells in your blood may help improve your immune system. This may reduce your risk of death or getting [opportunistic infections \(OIs\)](#) that can happen when your immune system is weak. [Read more about viral suppression](#).

Syntuza [does not cure](#) HIV infection or [AIDS](#). You must keep taking HIV medicines to control HIV infection and decrease HIV-related illnesses.

WHO SHOULD TAKE SYMTUZA?

Syntuza is a prescription four-drug fixed-dose combination medication to treat HIV infection in adults and

children who weigh at least 88 pounds (40 kg):

- who have not received HIV medicines in the past
- OR**
- to replace their current HIV medicines when their healthcare provider determines that they meet certain requirements

The safety and effectiveness of Symtuza has not been established in children who weigh less than 88 pounds (40 kg).

All people with HIV should be on ART to keep healthy AND not transmit the virus to others. You and your healthcare provider should consider your CD4 cell count, your viral load, any symptoms you are having, and your preferences when deciding which HIV medications are right for you. [Read more about U.S. ART guidelines.](#)

Symtuza provides four drugs in one pill. It can be more convenient to use Symtuza than some other combinations of drugs that must be taken separately or at different times of the day. This could mean fewer missed doses and better control of HIV. **Symtuza is used as a complete regimen for the treatment of HIV infection.**

WHO SHOULD NOT TAKE SYMTUZA?

Do not take Symtuza if you are allergic to darunavir, cobicistat, emtricitabine, tenofovir AF, or any of the ingredients in this drug.

Do not take Symtuza if you are taking any of the following medicines. Taking Symtuza with these medicines may affect how Symtuza works. Symtuza may cause serious or life-threatening side effects or death when used with these medicines:

- Alpha 1-adrenoreceptor antagonist: alfuzosin
- Gout medicine: colchicine (if you have liver or kidney problems)
- Seizure medicines: carbamazepine, phenobarbital, phenytoin
- Antipsychotic medicines: lurasidone, pimozide
- [Tuberculosis \(TB\)](#) medicine: rifampin
- Benzodiazepines: midazolam (when taken by mouth), triazolam
- Cholesterol medicines: lomitapide, lovastatin, simvastatin
- Ergot-containing medicines: dihydroergotamine, ergotamine tartrate, methylergonovine
- Heart medicines: dronedarone, ivabradine, ranolazine
- Heartburn and reflux medicine: cisapride
- [Hepatitis C virus \(HCV\)](#) medicines: elbasvir, grazoprevir
- Herbal product: St. John's Wort (*Hypericum perforatum*)
- Opioid antagonist: naloxegol
- PDE-5 inhibitor: sildenafil (when used for the treatment of pulmonary arterial hypertension [PAH])

Ask your healthcare provider or pharmacist if you are not sure if your medicine is one that is listed above. If you have taken any of these medicines in the past 4 weeks, talk to your healthcare provider or pharmacist before starting treatment with Symtuza.

Symtuza is not recommended in people who have severe kidney or liver disease.

WHAT SHOULD I TELL MY HEALTHCARE PROVIDER BEFORE TAKING SYMTUZA?

Before you take Symtuza, tell your healthcare provider about all of your medical conditions, and in particular if you:

- Have liver problems, including [hepatitis B virus \(HBV\)](#) or HCV infection
- Have [kidney problems](#)
- Are allergic to sulfa (sulfonamide)
- Have [diabetes](#)
- Have hemophilia

Talk to your healthcare provider if you are pregnant, you plan to become pregnant, you become pregnant, or think you may be pregnant during treatment with Symtuza. It is not known if Symtuza can harm your unborn baby. Symtuza should not be used during pregnancy because you may not have enough Symtuza in your body during pregnancy.

There is a pregnancy registry for people who take ARVs during pregnancy. The purpose of this registry is to collect information about the health of you and your baby and monitor outcomes in people exposed to ARVs during pregnancy. Talk to your healthcare provider about how you can take part in this registry. [Read more about pregnancy and HIV.](#)

Talk to your healthcare provider if you are breastfeeding or plan to breastfeed during treatment with Symtuza. At least one of the medicines in Symtuza (emtricitabine) can pass to your baby in your breastmilk. It is not known if the other medicines in Symtuza can pass into your breastmilk. Do not breastfeed if you have HIV because of the risk of passing HIV to your baby. Talk with your healthcare provider about the best way to feed your baby during treatment with Symtuza.

WHAT ABOUT DRUG RESISTANCE?

Many new copies of HIV are mutations. These new copies are slightly different from the original virus. Some mutations can keep multiplying even when you are taking an ARV. When this happens, the drug will stop working. This is called developing resistance to the drug. Sometimes, if your virus develops resistance to one ARV, it will also have resistance to other ARVs. This is called cross-resistance. [Read more about HIV drug resistance.](#)

Resistance can develop quickly. It is very important to take ARVs according to instructions, on schedule, and not to skip or reduce doses.

HOW IS SYMTUZA TAKEN?

Symtuza is taken by mouth as a tablet. Each Symtuza tablet contains 800 mg of darunavir, 150 mg of cobicistat, 200 mg of emtricitabine, and 10 mg of tenofovir AF. The recommended dosage of Symtuza for adults and children who weigh at least 88 pounds (40 kg) is one tablet once daily.

Take Symtuza at the same time each day with food.

WHAT ARE THE SIDE EFFECTS?

When you start any ARV, you may have temporary [side effects](#) such as headaches, nausea, indigestion, or a general sense of feeling ill. These side effects usually get better or disappear over time.

The most common side effects of Symtuza are [diarrhea](#), rash, nausea, [fatigue](#), headaches, stomach problems, and gas.

Symtuza can cause serious side effects including:

Worsening of HBV infection. Your healthcare provider will test you for HBV before or when you start treatment with Symtuza. If you have HBV infection and take Symtuza, your HBV may get worse (flareup) if you stop taking Symtuza. A flare-up is when your HBV infection suddenly returns in a worse way than before. Do not stop taking Symtuza without first talking to your healthcare provider. Do not run out of Symtuza. Refill your prescription or talk to your healthcare provider before your Symtuza is all gone. If you stop taking Symtuza, your healthcare provider will need to check your health often and do [blood tests](#) regularly for several months to check your HBV infection, or give you a medication to treat HBV. Tell your healthcare provider about any new or unusual symptoms you may have after you stop taking Symtuza.

Change in liver enzymes. People with a history of HBV or HCV infection or who have certain liver enzyme changes may have an increased risk of developing new or worsening liver problems during treatment with Symtuza. Liver problems can also happen during treatment with Symtuza in people without a history of liver disease. Your healthcare provider may need to do tests to check your liver enzymes before and during treatment with Symtuza.

Severe liver problems. In rare cases, severe liver problems can happen that can lead to death. Tell your healthcare provider right away if you get these symptoms:

- Skin or the white part of your eyes turns yellow
- Dark or “tea-colored” urine
- Light-colored stools (bowel movements)
- Loss of appetite for several days or longer
- Nausea or vomiting
- Stomach-area pain

Severe or life-threatening skin reactions or rash. Sometimes these skin reactions and skin rashes can become severe and require treatment in a hospital. Call your healthcare provider right away if you develop a rash. Stop taking Symtuza and call your healthcare provider right away if you develop any skin changes with symptoms below:

- Fever
- Tiredness
- Muscle or joint pain
- Blisters or skin lesions
- Mouth sores or ulcers
- Red or inflamed eyes, like “pink eye” (conjunctivitis)

Immune Reconstitution Inflammatory Syndrome (IRIS). [IRIS](#) is a side effect that can happen when you start taking HIV medications. Your immune system might get stronger and begin to fight infections that have been hidden in your body for a long time. This may result in an inflammatory response which may require

further evaluation and treatment. Tell your healthcare provider right away if you experience any new symptoms after starting treatment with Symtuza.

New or worse kidney problems, including kidney failure. Your healthcare provider should do blood and urine tests to check your kidneys before you start and during treatment with Symtuza. Your healthcare provider may tell you to stop taking Symtuza if you develop new or worse kidney problems during treatment with Symtuza.

Too much lactic acid in your blood (lactic acidosis). [Lactic acidosis](#) is a serious but rare medical emergency that can cause death. Tell your healthcare provider right away if you develop any of these symptoms:

- Weakness or being more tired than usual
- Being short of breath or fast breathing
- Cold or blue hands and feet
- Fast or abnormal heartbeat
- Unusual muscle pain
- Stomach pain with nausea and vomiting
- Feel dizzy or lightheaded

Diabetes and high blood sugar (hyperglycemia). Some people who take protease inhibitors including Symtuza can get high blood sugar, develop diabetes, or their diabetes can get worse. Tell your healthcare provider if you notice an increase in thirst or if you start urinating more often while taking Symtuza.

Changes in body fat. [Changes in body fat distribution or accumulation](#) have happened in some people taking HIV medicines, including an increased amount of fat in the upper back and neck (buffalo hump), in the breasts, and around the trunk. Loss of fat from the legs, arms, and face may also happen. The cause and long-term health effects of these body fat changes are not known.

Increased bleeding for hemophiliacs. Some people with hemophilia have increased bleeding with protease inhibitors.

These are not all the possible side effects of Symtuza. For more information, ask your healthcare provider or pharmacist. Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

HOW DOES SYMTUZA REACT WITH OTHER DRUGS?

All ARVs can [interact](#) with other drugs or supplements you are taking. These interactions can change the amount of each drug in your bloodstream and cause an under- or overdose. New interactions are constantly being identified. **Tell your healthcare provider about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Your healthcare provider can tell you if it is safe to take Symtuza with other medicines.

See above for a list of medications that should not be taken with Symtuza.

Symtuza is a complete regimen for the treatment of HIV infection; therefore, taking Symtuza with other ARVs for the treatment of HIV infection is not recommended.

MORE INFORMATION

Visit the [Syntuza website](#).

Visit the [Syntuza healthcare professional website](#).

Download the full [Prescribing Information](#).

Visit the [Janssen CarePath website](#) for Syntuza.

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