Symfi and Symfi-Lo

WHAT ARE SYMFI AND SYMFI-LO?

Symfi and Symfi-Lo are complete HIV regimens used as part of antiretroviral therapy (ART). Symfi and Symfi-Lo contain three antiretroviral drugs (ARVs) combined in one tablet:

- efavirenz (EFV, Sustiva)
- lamivudine (3TC, Epivir)
- tenofovir disoproxil fumarate (tenofovir DF, TDF, Viread)

The FDA approved Symfi and Symfi-Lo in 2018 as ARVs for people with HIV infection. Generic versions have been approved for sale outside the U.S. under the PEPFAR program. Symfi and Symfi-Lo are manufactured by Viatris. Symfi and Symfi-Lo contain the same combination of drugs but have a different dosage of efavirenz (see below).

One of the drugs in Symfi and Symfi-Lo, efavirenz, is a type of drug called a non-nucleoside reverse transcriptase inhibitor (NNRTIs). Two of the drugs in Symfi and Symfi-Lo, emtricitabine and tenofovir DF, are nucleoside reverse transcriptase inhibitors (NRTIs). NNRTIs and 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 complete HIV regimens to treat HIV infection, Symfi and Symfi-Lo 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.

Symfi and Symfi-Lo do not cure HIV infection or AIDS. You must keep taking HIV medicines to control HIV infection and decrease HIV-related illnesses.

WHO SHOULD TAKE SYMFI AND SYMFI-LO?

Symfi is a prescription three-drug fixed-dose combination medication to treat HIV infection in adults and children who weigh at least 88 pounds (40 kg). The safety and effectiveness of Symfi has not been established in children who weigh less than 88 pounds (40 kg). Symfi has not been carefully studied in the elderly (65 years of age and older).

Symfi-Lo is a prescription three-drug fixed-dose combination medication to treat HIV infection in adults and children who weigh at least 77 pounds (35 kg). The safety and effectiveness of Symfi-Lo has not been established in children who weigh less than 77 pounds (35 kg). Symfi-Lo has not been carefully studied in the elderly (65 years of age and older).

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.

Symfi and Symfi-Lo each provide three drugs in one pill. It can be more convenient to use Symfi or Symfi-Lo 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. **Symfi and Symfi-Lo are each used as a complete regimen for the treatment of HIV.**

WHO SHOULD NOT TAKE SYMFI AND SYMFI-LO?

Do not take Symfi or Symfi-Lo if you are allergic to efavirenz, lamivudine, tenofovir DF, or any of the ingredients in these drugs.

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

- Hepatitis C virus (HCV) medicines: elbasvir, grazoprevir
- Medicines that contain sorbitol

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 four weeks, talk to your healthcare provider or pharmacist before starting treatment with Symfi or Symfi-Lo.

Symfi is not recommended in people with severe kidney disease, end-stage renal disease (ESRD) requiring hemodialysis, or people with moderate to severe liver disease.

WHAT SHOULD I TELL MY HEALTHCARE PROVIDER BEFORE TAKING SYMFI AND SYMFI-LO?

Before you take Symfi or Symfi-Lo, 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, including end-stage renal disease (ESRD) that requires dialysis
- Have a history of mental health problems
- Have a history of drug or alcohol abuse
- Have a heart problem, including QT prolongation
- Have bone problems, including a history of bone fractures
- Have a history of seizures

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 Symfi or Symfi-Lo. If you are able to become pregnant, your healthcare provider should do a pregnancy test before you start Symfi or Symfi-Lo and you should use effective birth control during treatment with Symfi or Symfi-Lo and for 12 weeks after stopping treatment. A barrier form of birth control should always be used along with another type of birth control.

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 Symfi or Symfi-Lo. 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.

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 ARE SYMFI AND SYMFI-LO TAKEN?

Symfi is taken by mouth as a tablet. Each Symfi tablet contains 600 mg of efavirenz, 300 mg of lamivudine, and 300 mg of tenofovir DF. The recommended dosage of Symfi for adults and children who weigh at least 88 pounds (40 kg) is one tablet once daily.

Symfi Lo is taken by mouth as a tablet. Each Symfi-Lo tablet contains 400 mg of efavirenz, 300 mg of lamivudine, and 300 mg of tenofovir DF. The recommended dosage of Symfi-Lo for adults and children who weigh at least 77 pounds (35 kg) is one tablet once daily.

Take Symfi or Symfi-Lo at bedtime on an empty stomach. Taking Symfi or Symfi-Lo at bedtime may make some side effects less bothersome.

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 Symfi are trouble concentrating, headache, not feeling well, nasal signs and symptoms, rash, trouble sleeping, depression, cough, abnormal dreams, nausea, tiredness, diarrhea, dizziness, pain, and weakness.

The most common side effects of Symfi-Lo are rash and dizziness.

Symfi and Symfi-Lo can cause serious side effects including:

Worsening of HBV infection. Your healthcare provider will test you for HBV before starting treatment with Symfi or Symfi-Lo. It is not known if Symfi or Symfi-Lo is safe and effective in people who have both HIV and HBV infection. If you have HBV infection and take Symfi or Symfi-Lo, your HBV may get worse (flareup) if you stop taking Symfi or Symfi-Lo. A flare-up is when your HBV infection suddenly returns in a worse way than before. Do not stop taking Symfi or Symfi-Lo without first talking to your healthcare provider. Do not run out of Symfi or Symfi-Lo. Refill your prescription or talk to your healthcare provider before your Symfi or Symfi-Lo is all gone. If you stop taking Symfi or Symfi-Lo, your healthcare provider will need to check your health often and do blood tests regularly for several months to check your liver. Tell your healthcare provider about any new or unusual

symptoms you may have after you stop taking Symfi or Symfi-Lo.

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

Severe liver problems. In rare cases, severe liver problems can happen that can lead to death. Your liver may become large (hepatomegaly) and you may develop fat in your liver (steatosis). Inflammation of your liver (hepatitis) that can lead to liver failure requiring a liver transplant has been reported in some people treated with Symfi or Symfi-Lo. Your healthcare provider may do blood tests to check your liver before and during treatment with SYMFI. Tell your healthcare provider right away if you get these symptoms:

- Your skin or the white part of your eyes turns yellow (jaundice)
- Dark or “tea-colored” urine
- Light-colored stools (bowel movements)
- Confusion
- Tiredness
- Loss of appetite for several days or longer
- Nausea and vomiting
- Pain, aching, or tenderness on the right side of your stomach-area
- Weakness
- Stomach (abdomen) swelling

You may be more likely to get lactic acidosis or serious liver problems if you are assigned female at birth (AFAB) or are very overweight (obese).

Rash. Rash is a serious side effect but may also be common. Rashes will usually go away without any change in your treatment. Tell your healthcare provider right away if you develop a rash during treatment with Atripla.

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 Symfi or Symfi-Lo. Tell your healthcare provider if you get signs and symptoms of kidney problems, including bone pain that does not go away or worsening bone pain, pain in your arms, hands, legs or feet, broken (fractured) bones, muscle pain, or weakness.

Mental health problems. Tell your healthcare provider right away if you get any of the following symptoms:

- Feel sad or hopeless
- Feel anxious or restless
- Do not trust other people
- Hear or see things that are not real
- Are not able to move or speak normally
- Have thoughts of hurting yourself (suicide) or have tried to hurt yourself or others
- Are not able to tell the difference between what is true or real and what is false or unreal

Nervous system symptoms. Nervous system problems are common in people who take Symfi or Symfi-Lo and can be severe. These symptoms usually begin during the first or second day of treatment with Symfi or Symfi-Lo and usually go away after 2-4 weeks of treatment. Some symptoms may occur months to years after beginning Symfi or Symfi-Lo therapy. These symptoms may become worse if you drink alcohol, take a medicine for mental health problems, or use certain street drugs during treatment with Symfi or Symfi-Lo. Symptoms may include:

- Dizziness
- Trouble sleeping
- Unusual dreams
- Trouble concentrating
- Drowsiness
- Lack of coordination or balance

If you have dizziness, trouble concentrating or drowsiness, do not drive a car, use machinery, or do anything that needs you to be alert. Some nervous system symptoms (e.g., confusion, slow thoughts and physical movement, and delusions [false beliefs]

or hallucinations [seeing or hearing things that others do not see or hear]) may occur months to years after beginning Symfi or Symfi-Lo therapy. Promptly contact your healthcare provider should any of these symptoms occur.

Skin reactions and allergic reactions. Skin reactions or rash can happen and can sometimes be severe. Skin rash usually goes away without any change in treatment. If you develop a rash or a rash with any of the following symptoms, call your healthcare provider right away:

- Itching
- Fever
- Swelling of your face
- Blisters or skin lesions
- Peeling skin
- Mouth sores
- Red or inflamed eyes

Inflammation of the pancreas (pancreatitis). Children may be at risk for developing pancreatitis during treatment with Symfi or Symfi-Lo if they have taken nucleoside analogue medicines (NRTIs or NNRTIs) in the past, have a history of pancreatitis, or have other risk factors for pancreatitis. Call your healthcare provider right away if your child develops signs and symptoms of pancreatitis including severe upper stomach-area pain, with or without nausea and vomiting. Your healthcare provider may tell you to stop giving Symfi or Symfi-Lo to your child if their symptoms and blood test results show that your child may have pancreatitis.

Seizures. Seizures are more likely to happen if you have had seizures in the past.

Increases in blood fat levels (cholesterol and triglycerides). Your healthcare provider will check your blood fat levels before and during treatment with Symfi or Symfi-Lo.

Bone problems. Bone problems can happen in some people who take Symfi or Symfi-Lo. Bone problems include bone pain or softening or thinning of bones, which may lead to fractures. Your healthcare provider may need to do tests to check your bones. Tell your healthcare provider if you have any bone pain, pain in your hands or feet, or muscle pain or weakness during treatment with Symfi or Symfi-Lo.

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 Symfi or Symfi-Lo.

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) 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.

Changes in the electrical activity of your heart called QT prolongation. QT prolongation can cause irregular heartbeats that can be life-threatening. Tell your healthcare provider if you feel faint, lightheaded, dizzy, or feel your heart beating irregularly or fast during treatment with Symfi or Symfi-Lo.

These are not all the possible side effects of Symfi or Symfi-Lo. 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 DO SYMFI AND SYMFI-LO 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 Symfi or Symfi-Lo with other medicines.

See above for a list of medicines that should not be taken with Symfi and Symfi-Lo.

Symfi and Symfi-Lo are complete regimens for the treatment of HIV infection; therefore, taking Symfi or Symfi-Lo with other ARVs for the treatment of HIV infection is not recommended.

MORE INFORMATION

Symfi

Download the full Prescribing Information.

Download the Patient Information leaflet.

Symfi-Lo

Visit the Symfi-Lo website.

Visit the Symfi-Lo healthcare professional website.

Download the full Prescribing Information.

Download the Patient Information leaflet.

Check out the Viatris Copay Program for Symfi-Lo.

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