



PATIENT & CAREGIVER EDUCATION

Efavirenz, Emtricitabine, and Tenofovir Disoproxil Fumarate

This information from Lexicomp[®] explains what you need to know about this medication, including what it's used for, how to take it, its side effects, and when to call your healthcare provider.

Brand Names: Canada

APO-Efavir-Emtricitab-Tenofo; Atripla [DSC]; AURO-Efav-Emtri-Tenof; JAMP-Efavirenz/Emtricit/Tenofo; MYLAN-Efavir/Emtricitab/Tenofo; PMS-Efav-Emtri-Tenofovir; RIVA-Efavirenz/Emtricit/Tenofo; SANDOZ Efavirenz/Emtri/Tenofov [DSC]; TEVA-Efavir/Emtricitab/Tenofov

Warning

- Hepatitis B has gotten worse when this drug was stopped in some people with hepatitis B. Close follow-up for a few months is needed when therapy is stopped in people who have hepatitis B. Do not stop taking this drug without calling your doctor.
- This drug is not approved to treat hepatitis B. Hepatitis B testing needs to be done before taking this drug.

What is this drug used for?

- It is used to treat HIV infection.

What do I need to tell my doctor BEFORE I take this drug?

- If you are allergic to this drug; any part of this drug; or any other drugs, foods, or substances. Tell your doctor about the allergy and what signs you had.
- If you have had red, blistered, swollen, or peeling skin after taking efavirenz.
- If you have any of these health problems: Kidney disease or liver disease.
- If you weigh less than 88 pounds (40 kilograms). This

drug is not for use in people who weigh less than 88 pounds (40 kilograms).

- If you take any drugs (prescription or OTC, natural products, vitamins) that must not be taken with this drug, like certain drugs that are used for HIV, infections, seizures, and others. There are many drugs that must not be taken with this drug.
- If you are taking another drug that has the same drug in it.
- If you are taking any drugs that can raise the chance of kidney problems. There are many drugs that can do this. Ask your doctor or pharmacist if you are not sure.
- If you are pregnant, may become pregnant, or are breast-feeding. Before taking this drug, you will need to talk about the benefits and risks to you and the baby. You will also need to talk about the best way to prevent passing HIV to the baby.

This is not a list of all drugs or health problems that interact with this drug.

This drug interacts with many other drugs. The chance of severe, life-threatening, or deadly side effects may be raised. Tell your doctor and pharmacist about all of your drugs (prescription or OTC, natural products, vitamins)

and health problems. You must check to make sure that it is safe for you to take this drug with all of your drugs and health problems. Do not start, stop, or change the dose of any drug without checking with your doctor.

What are some things I need to know or do while I take this drug?

- Tell all of your health care providers that you take this drug. This includes your doctors, nurses, pharmacists, and dentists.
- Avoid driving and doing other tasks or actions that call for you to be alert until you see how this drug affects you.
- Talk with your doctor before you use alcohol, marijuana or other forms of cannabis, or prescription or OTC drugs that may slow your actions.
- Take calcium and vitamin D as you were told by your doctor.
- Have your blood work and other lab tests checked as you have been told by your doctor. Some people may also need to have heart rhythm checked with an ECG.
- This drug may affect certain lab tests. Tell all of your health care providers and lab workers that you take this drug.
- This drug is not a cure for HIV. Keep taking this drug

as you have been told by your doctor or other health care provider, even if you feel well. Be sure to stay under the care of your doctor and have regular appointments.

- This drug helps to lower how much HIV is in the blood. Lowering the amount of HIV in the blood until it is not detected on blood tests can help lower the risk of spreading HIV to others. There are also other ways to help prevent the spread of HIV to others. This includes using condoms during sex and not sharing needles and other injection equipment. Talk with your doctor or other health care provider about the best way to prevent spreading HIV to others.
- Bone problems like bone pain, soft bones, and thin bones have happened. This may lead to broken bones. You may need to have a bone test.
- Rarely, this drug may cause a swollen liver and a buildup of acid in the blood. Sometimes, this may be deadly. The risk may be higher in females, in overweight people, and in people who have taken drugs like this one for a long time.
- A type of abnormal heartbeat (prolonged QT interval) can happen with this drug. Call your doctor right away if you have a fast heartbeat, a heartbeat that does not feel normal, or if you pass out.

- Kidney problems like kidney failure have happened with this drug. Tell your doctor if you have ever had kidney problems.
- Liver problems have happened with this drug. Sometimes these problems have been severe, leading to liver transplant or death. Liver problems may happen in people with or without liver disease. Talk with the doctor.
- Birth control pills and other hormone-based birth control may not work as well to prevent pregnancy. Use some other kind of birth control also like a condom when taking this drug.
- If you are able to get pregnant, your doctor may have you take a pregnancy test before starting this drug.
- Talk to your doctor about using birth control to prevent pregnancy while you take this drug and for some time after your last dose. If you get pregnant, call your doctor right away.

What are some side effects that I need to call my doctor about right away?

WARNING/CAUTION: Even though it may be rare, some people may have very bad and sometimes deadly side effects when taking a drug. Tell your doctor or get medical help right away if you have any of the following

signs or symptoms that may be related to a very bad side effect:

- Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing, swallowing, or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat.
- Signs of kidney problems like unable to pass urine, change in how much urine is passed, blood in the urine, or a big weight gain.
- Signs of too much lactic acid in the blood (lactic acidosis) like fast breathing, fast heartbeat, a heartbeat that does not feel normal, very bad upset stomach or throwing up, feeling very sleepy, shortness of breath, feeling very tired or weak, very bad dizziness, feeling cold, or muscle pain or cramps.
- Signs of liver problems like dark urine, tiredness, decreased appetite, upset stomach or stomach pain, light-colored stools, throwing up, or yellow skin or eyes.
- Signs of depression, suicidal thoughts, emotional ups and downs, abnormal thinking, anxiety, or lack of interest in life.

- Memory problems or loss.
- Bone pain.
- Muscle pain or weakness.
- Pain in arms or legs.
- Seizures.
- Change in body fat.
- Changes in your immune system can happen when you start taking drugs to treat HIV. If you have an infection that you did not know you had, it may show up when you take this drug. Tell your doctor right away if you have any new signs after you start this drug, even after taking it for several months. This includes signs of infection like fever, sore throat, weakness, cough, or shortness of breath.
- Severe nervous system problems have happened. These may include feeling confused, behavior or mood changes, balance problems, other movement problems, or hallucinations (seeing or hearing things that are not there). Sometimes, this has happened months to years after starting this drug. Call your doctor right away if you have any of these effects.
- A severe skin reaction (Stevens-Johnson syndrome/toxic epidermal necrolysis) may happen. It can cause severe health problems that may not go

away, and sometimes death. Get medical help right away if you have signs like red, swollen, blistered, or peeling skin (with or without fever); red or irritated eyes; or sores in your mouth, throat, nose, or eyes.

What are some other side effects of this drug?

All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your doctor or get medical help if any of these side effects or any other side effects bother you or do not go away:

- Headache.
- Diarrhea, upset stomach, or throwing up.
- Change in color of skin.
- Feeling tired or weak.
- Signs of a common cold.
- Nervous system problems are common with this drug. These may include dizziness, sleepiness, trouble sleeping or focusing, or abnormal dreams. Most of the time, this goes away after 2 to 4 weeks. Taking this drug at bedtime may help with these effects. If you feel dizzy, sleepy, or have trouble focusing, avoid driving and doing other tasks or actions that call for you to be alert. Call your doctor if these effects last,

they bother you, or are severe.

These are not all of the side effects that may occur. If you have questions about side effects, call your doctor. Call your doctor for medical advice about side effects.

You may report side effects to your national health agency.

You may report side effects to the FDA at 1-800-332-1088. You may also report side effects at <https://www.fda.gov/medwatch>.

How is this drug best taken?

Use this drug as ordered by your doctor. Read all information given to you. Follow all instructions closely.

- Take on an empty stomach.
- Take with a full glass of water.
- Taking this drug at bedtime may help with some side effects.
- It is important that you do not miss or skip a dose of this drug during treatment.

What do I do if I miss a dose?

- Take a missed dose as soon as you think about it.
- If it is close to the time for your next dose, skip the

missed dose and go back to your normal time.

- Do not take 2 doses at the same time or extra doses.
- If you are not sure what to do if you miss a dose, call your doctor.

How do I store and/or throw out this drug?

- Store tablets in the original container at room temperature. Keep the cap tightly closed.
- Store in a dry place. Do not store in a bathroom.
- Keep all drugs in a safe place. Keep all drugs out of the reach of children and pets.
- Throw away unused or expired drugs. Do not flush down a toilet or pour down a drain unless you are told to do so. Check with your pharmacist if you have questions about the best way to throw out drugs. There may be drug take-back programs in your area.

General drug facts

- If your symptoms or health problems do not get better or if they become worse, call your doctor.
- Do not share your drugs with others and do not take anyone else's drugs.
- Some drugs may have another patient information leaflet. If you have any questions about this drug,

please talk with your doctor, nurse, pharmacist, or other health care provider.

- Some drugs may have another patient information leaflet. Check with your pharmacist. If you have any questions about this drug, please talk with your doctor, nurse, pharmacist, or other health care provider.
- If you think there has been an overdose, call your poison control center or get medical care right away. Be ready to tell or show what was taken, how much, and when it happened.

Consumer Information Use and Disclaimer

This generalized information is a limited summary of diagnosis, treatment, and/or medication information. It is not meant to be comprehensive and should be used as a tool to help the user understand and/or assess potential diagnostic and treatment options. It does NOT include all information about conditions, treatments, medications, side effects, or risks that may apply to a specific patient. It is not intended to be medical advice or a substitute for the medical advice, diagnosis, or treatment of a health care provider based on the health care provider's examination and assessment of a patient's specific and unique circumstances. Patients must speak with a health care provider for complete

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If you have questions or concerns, contact your healthcare provider. A member of your care team will answer Monday through Friday from 9 a.m. to 5 p.m. Outside those hours, you can leave a message or talk with another MSK provider. There is always a doctor or nurse on call. If you're not sure how to reach your healthcare provider, call 212-639-2000.

For more resources, visit www.mskcc.org/pe to search our virtual library.

Efavirenz, Emtricitabine, and Tenofovir Disoproxil Fumarate -
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