PATIENT & CAREGIVER EDUCATION

Efavirenz, Emtricitabine, and Tenofovir Disoproxil

This information from UpToDate® Lexidrug™ 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; AURO-Efav-Emtri-Tenof; JAMP-Efavirenz/Emtricit/Tenofo; MYLAN-Efavir/Emtricitab/Tenofo; PMS-Efav-Emtri-Tenofovir; RIVA-Efavirenz/Emtricit/Tenofo [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 several months is needed when therapy is stopped in people who have hepatitis B. Do not stop giving this drug to your child without calling your child's doctor.
- This drug is not approved to treat hepatitis B. Hepatitis B testing needs to be done before your child takes this drug.

What is this drug used for?

- It is used to treat HIV infection.

What do I need to tell the doctor BEFORE my child takes this drug?

- If your child is allergic to this drug; any part of this drug; or any other drugs, foods, or substances. Tell the doctor about the allergy and what signs your child had.
- If your child has had red, blistered, swollen, or peeling skin after taking efavirenz.
- If your child has any of these health problems: Kidney disease or liver disease.

- If your child weighs less than 88 pounds (40 kilograms). This drug is not for use in children who weigh less than 88 pounds (40 kilograms).
- If your child takes 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 your child is taking another drug that has the same drug in it.
- If your child is taking any drugs that can raise the chance of kidney problems. There are many drugs that can do this. Ask the doctor or pharmacist if you are not sure.
- If your child is pregnant, may become pregnant, or is breast-feeding a baby. Before giving this drug to your child, you will need to talk about the benefits and risks to your child and the baby. You will also need to talk about the best way for your child 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 the doctor and pharmacist about all of your

child's drugs (prescription or OTC, natural products, vitamins) and health problems. You must check to make sure that it is safe to give this drug with all of your child's other drugs and health problems. Do not start, stop, or change the dose of any drug your child takes without checking with the doctor.

What are some things I need to know or do while my child takes this drug?

- Tell all of your child's health care providers that your child is taking this drug. This includes your child's doctors, nurses, pharmacists, and dentists.
- Have your child avoid tasks or actions that call for alertness until you see how this drug affects your child. These are things like riding a bike, playing sports, or using items such as scissors, lawnmowers, electric scooters, toy cars, or motorized vehicles.
- Alcohol may interact with this drug. Be sure your child does not drink alcohol.
- Talk with your child's doctor before your child uses marijuana, other forms of cannabis, or prescription or OTC drugs that may slow your child's actions.
- Give calcium and vitamin D as you were told by your child's doctor.
- Have your child's blood work and other lab tests

checked as you have been told by the 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 child's health care providers and lab workers that your child takes this drug.
- This drug is not a cure for HIV. Keep giving this drug to your child as you have been told by the doctor or other health care provider, even if your child feels well. Be sure your child stays under the care of the doctor and has 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 child's 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. Your child 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.

- 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.
- If your child is able to get pregnant, the doctor may have your child take a pregnancy test before starting this drug.

If your child is or may be sexually active:

- Birth control pills and other hormone-based birth control may not work as well to prevent pregnancy. Be sure your child uses some other kind of birth control also, like a condom, when taking this drug.
- Talk to the doctor about having your child use birth control to prevent pregnancy while taking this drug and for some time after the last dose. If your child gets pregnant, call the doctor right away.

What are some side effects that I need to call my child's 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 child's doctor or get medical help right away if your child has 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 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 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 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 child's immune system can happen when your child starts taking drugs to treat HIV. If your child has an infection that you did not know was there, it may show up when your child takes this drug. Tell your child's doctor right away if your child has any new signs after starting 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 the doctor right away if your child has 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 your child has signs like red, swollen, blistered, or peeling skin (with or without fever); red or irritated eyes; or sores in the mouth, throat, nose, or eyes.
- A type of abnormal heartbeat (prolonged QT interval) can happen with this drug. Call the doctor right away if your child has a fast heartbeat, a heartbeat that does not feel normal, or if your child passes out.

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 child's doctor or get medical help if any of these side effects or any other side effects bother your child 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. Giving this drug at bedtime may help with these effects. If your child feels dizzy, sleepy, or has trouble focusing, have your child avoid tasks or actions that call for alertness. Call the doctor if these effects last, they bother your child, or are severe.

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

You may report side effects to your national health agency.

How is this drug best given?

Give this drug as ordered by your child's doctor. Read all information given to you. Follow all instructions closely.

- Give on an empty stomach.
- Give this drug with a full glass of water.
- Giving this drug at bedtime may help with some side effects.
- It is important that your child does not miss or skip a dose of this drug during treatment.

What do I do if my child misses a dose?

- Give a missed dose as soon as you think about it.
- If it is close to the time for your child's next dose, skip the missed dose and go back to your child's normal time.
- Do not give 2 doses at the same time or extra doses.
- If you are not sure what to do if your child misses a dose, call the 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 child's symptoms or health problems do not get better or if they become worse, call your child's doctor.

- Do not share your child's drug with others and do not give anyone else's drug to your child.
- Some drugs may have another patient information leaflet. If you have any questions about this drug, please talk with your child's 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.

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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.

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