

Emtricitabine, Rilpivirine, 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: US

Complera

Brand Names: Canada

Complera

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 giving this drug to your child without calling your child's doctor.
- Hepatitis B testing needs to be done as you were told by the doctor. Talk with the doctor.

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 kidney disease.
- If your child takes any drugs (prescription or OTC, natural products, vitamins) that must not be taken with this drug, like some other drugs used for HIV or certain drugs used for seizures, infection, or stomach or bowel problems. There are many drugs that must not be taken with this drug.

If your child is breast-feeding a baby:

- Be sure your child does not breast-feed a baby while taking this drug.

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.
- 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.
- Give calcium and vitamin D as you were told by your child's doctor.
- Have blood work checked as you have been told by the doctor. Talk with the

doctor.

- Have your child's urine checked as you have been told by the doctor.
- This drug is not a cure for HIV. Be sure your child stays under the care of the doctor.
- This drug does not stop the spread of diseases like HIV or hepatitis that are passed through blood. Be sure needles and other things like toothbrushes or razors are not shared.
- Kidney problems like kidney failure have happened with this drug. Tell your child's doctor if your child has ever had kidney problems.
- 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.

If your child is or may be sexually active:

- This drug does not stop the spread of diseases like HIV or hepatitis that are passed through having sex. Be sure your child does not have any kind of sex without using a latex or polyurethane condom.

If your child is pregnant:

- Tell the doctor if your child is pregnant or becomes pregnant. You will need to talk about the benefits and risks of your child using this drug while pregnant.

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 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.
- A burning, numbness, or tingling feeling that is not normal.
- Bone pain.
- Muscle pain or weakness.
- Pain in arms or legs.
- 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.
- If your child has liver problems like hepatitis B or C, talk with your child's doctor. Liver problems have gotten worse with this drug. Call your child's doctor right away if your child has signs of liver problems like dark urine, feeling tired, not hungry, upset stomach or stomach pain, light-colored stools, throwing up, or yellow skin or eyes.
- Very bad skin and allergic reactions have happened with this drug. Skin reactions have happened along with fever or problems in body organs like the liver. Call the doctor right away if your child has red, swollen, blistered, or peeling skin (with or without fever); red or irritated eyes; sores in the mouth, throat, nose, or eyes; trouble swallowing; or signs of liver problems like dark urine, feeling tired, not hungry, upset stomach or stomach pain, light-colored stools, throwing up, or yellow skin 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 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.
- Upset stomach or throwing up.
- Stomach pain or diarrhea.
- Trouble sleeping.
- Feeling dizzy, sleepy, tired, or weak.
- Strange or odd dreams.
- Nose or throat irritation.
- Signs of a common cold.
- Joint pain.
- Back pain.

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.

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 given?

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

- Give this drug with food.
- Do not use a protein drink in place of food.

- Do not give antacids within 2 hours before this drug or 4 hours after this drug.
- Do not give cimetidine, famotidine, nizatidine, or ranitidine within 12 hours before or 4 hours after this drug.
- Keep giving this drug to your child as you have been told by your child's doctor or other health care provider, even if your child feels well.
- 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, with food.
- If it has been 12 hours or more since the missed 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 in the original container at room temperature.
- Keep lid 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 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 information should not be used to decide whether or not to take this medicine or any other medicine. Only the healthcare provider has the knowledge and training to decide which medicines are right for a specific patient. This information does not endorse any medicine as safe, effective, or approved for treating any patient or health condition. This is only a brief summary of general information about this medicine. It does NOT include all information about the possible uses, directions, warnings, precautions, interactions, adverse effects, or risks that may apply to this medicine. This information is not specific medical advice and does not replace information you receive from the healthcare provider. You must talk with the healthcare provider for complete information about the risks and benefits of using this medicine. The use of this information is governed by the Lexicomp End User License Agreement, available at

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If you have any questions, contact a member of your healthcare team directly. If you're a patient at MSK and you need to reach a provider after 5:00 PM, during the weekend, or on a holiday, call 212-639-2000.

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

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