

Patient Information
EMTRIVA® (em-treev'-ah) Capsules
EMTRIVA Oral Solution

Generic name: emtricitabine (em tri SIT uh bean)

Read the Patient Information that comes with EMTRIVA before you start using it and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or treatment.

You should stay under a healthcare provider's care when taking EMTRIVA. **Do not change or stop your medicine without first talking with your healthcare provider.** Talk to your healthcare provider or pharmacist if you have any questions about EMTRIVA.

What is the most important information I should know about EMTRIVA?

- **Some people who have taken medicines like EMTRIVA (a nucleoside analog) have developed a serious condition called lactic acidosis** (buildup of an acid in the blood). Lactic acidosis can be a medical emergency and may need to be treated in the hospital. **Call your healthcare provider right away if you get the following signs of lactic acidosis.**
 - You feel very weak or tired.
 - You have unusual (not normal) muscle pain.
 - You have trouble breathing.
 - You have stomach pain with nausea and vomiting.
 - You feel cold, especially in your arm and legs.
 - You feel dizzy or lightheaded.
 - You have a fast or irregular heartbeat.
- **Some people who have taken medicines like EMTRIVA have developed serious liver problems called hepatotoxicity**, with liver enlargement (hepatomegaly) and fat in the liver (steatosis). **Call your healthcare provider right away if you get the following signs of liver problems.**
 - Your skin or the white part of your eyes turns yellow (jaundice).
 - Your urine turns dark.
 - Your bowel movements (stools) turn light in color.
 - You don't feel like eating food for several days or longer.
 - You feel sick to your stomach (nausea).
 - You have lower stomach area (abdominal) pain.
- **You may be more likely to get lactic acidosis or liver problems** if you are female, very overweight (obese), or have been taking nucleoside analog medicines, like EMTRIVA, for a long time.
- **If you are also infected with the Hepatitis B Virus (HBV), you** need close medical follow-up for several months after stopping treatment with EMTRIVA. Follow-up includes medical exams and blood tests to check for HBV that is getting worse. **Patients with HBV infection, who take EMTRIVA and then**

stop it, may get “flare-ups” of their hepatitis. A “flare-up” is when the disease suddenly returns in a worse way than before.

What is EMTRIVA?

EMTRIVA is a type of medicine called an HIV (human immunodeficiency virus) nucleoside reverse transcriptase inhibitor (NRTI). EMTRIVA is always used with other anti-HIV medicines to treat people with HIV infection. **EMTRIVA is for adults and children, but has not been studied fully in adults over age 65.**

HIV infection destroys CD4 (T) cells, which are important to the immune system. The immune system helps fight infection. After a large number of T cells are destroyed, acquired immune deficiency syndrome (AIDS) develops.

EMTRIVA helps to block HIV reverse transcriptase, a chemical in your body (enzyme) that is needed for HIV to multiply. EMTRIVA may lower the amount of HIV in the blood (viral load). EMTRIVA may also help to increase the number of T cells called CD4 cells. Lowering the amount of HIV in the blood lowers the chance of death or infections that happen when your immune system is weak (opportunistic infections).

EMTRIVA does not cure HIV infection or AIDS. The long-term effects of EMTRIVA are not known at this time. People taking EMTRIVA may still get opportunistic infections or other conditions that happen with HIV infection. Opportunistic infections are infections that develop because the immune system is weak. Some of these conditions are pneumonia, herpes virus infections, and *Mycobacterium avium* complex (MAC) infections. **It is very important that you see your healthcare provider regularly while taking EMTRIVA.**

EMTRIVA does not lower your chance of passing HIV to other people through sexual contact, sharing needles, or being exposed to your blood. For your health and the health of others, it is important to always practice safer sex by using a latex or polyurethane condom or other barrier to lower the chance of sexual contact with semen, vaginal secretions, or blood. Never use or share dirty needles.

Who should not take EMTRIVA?

- Do not take EMTRIVA if you are allergic to EMTRIVA or any of its ingredients. The active ingredient is emtricitabine. See the end of this leaflet for a complete list of ingredients.
- Do not take EMTRIVA if you are already taking ATRIPLA™, TRUVADA®, Combivir, Epivir, Epivir-HBV, Epzicom, or Trizivir because these medicines contain the same or similar active ingredients.

What should I tell my healthcare provider before taking EMTRIVA?

Tell your healthcare provider

- **If you are pregnant or planning to become pregnant.** We do not know if EMTRIVA can harm your unborn child. You and your healthcare provider will need to decide if EMTRIVA is right for you. If you use EMTRIVA while you are pregnant, talk to your healthcare provider about how you can be on the EMTRIVA Antiviral Pregnancy Registry.

- **If you are breast-feeding.** You should not breast feed if you are HIV-positive because of the chance of passing the HIV virus to your baby. Also, it is not known if EMTRIVA can pass into your breast milk and if it can harm your baby. If you are a woman who has or will have a baby, talk with your healthcare provider about the best way to feed your baby.
- **If you have kidney problems.** You may need to take EMTRIVA less often.
- **If you have any liver problems including Hepatitis B Virus infection.**
- **Tell your healthcare provider about all your medical conditions.**
- **Tell your healthcare provider about all the medicines you take** such as prescription and non-prescription medicines and dietary supplements. Keep a complete list of all the medicines that you take. Make a new list when medicines are added or stopped. Give copies of this list to all of your healthcare providers and pharmacist **every** time you visit or fill a prescription.

How should I take EMTRIVA?

- Take EMTRIVA by mouth exactly as your healthcare provider prescribed it. Follow the directions from your healthcare provider, exactly as written on the label.
- Dosing in adults: The usual dose of EMTRIVA is 1 capsule once a day.
- Dosing in children: The child's doctor will calculate the right dose of EMTRIVA (oral solution or capsule) based on the child's weight.
- EMTRIVA is always used with other anti-HIV medicines.
- EMTRIVA may be taken with or without a meal. Food does not affect how EMTRIVA works.
- If you forget to take EMTRIVA, take it as soon as you remember that day. **Do not** take more than 1 dose of EMTRIVA in a day. **Do not** take 2 doses at the same time. Call your healthcare provider or pharmacist if you are not sure what to do. **It is important that you do not miss any doses of EMTRIVA or your other anti-HIV medicines.**
- When your EMTRIVA supply starts to run low, get more from your healthcare provider or pharmacy. This is very important because the amount of virus in your blood may increase if the medicine is stopped for even a short time. The virus may develop resistance to EMTRIVA and become harder to treat.
- Stay under a healthcare provider's care when taking EMTRIVA. Do not change your treatment or stop treatment without first talking with your healthcare provider.
- If you take too much EMTRIVA, call your local poison control center or emergency room right away.

What should I avoid while taking EMTRIVA?

- **Do not breast-feed.** See "What should I tell my healthcare provider before taking EMTRIVA?" Talk with your healthcare provider about the best way to feed your baby.

- **Avoid doing things that can spread HIV infection** since EMTRIVA doesn't stop you from passing the HIV infection to others.
- **Do not share needles or other injection equipment.**
- **Do not share personal items that can have blood or body fluids on them, like toothbrushes or razor blades.**
- **Do not have any kind of sex without protection.** Always practice safer sex by using a latex or polyurethane condom or other barrier to reduce the chance of sexual contact with semen, vaginal secretions, or blood.

What are the possible side effects of EMTRIVA?

EMTRIVA may cause the following serious side effects (see “What is the most important information I should know about EMTRIVA?”):

- **lactic acidosis** (buildup of an acid in the blood). Lactic acidosis can be a medical emergency and may need to be treated in the hospital. **Call your doctor right away if you get signs of lactic acidosis.** (see “What is the most important information I should know about EMTRIVA?”)
- **serious liver problems (hepatotoxicity)**, with liver enlargement (hepatomegaly) and fat in the liver (steatosis). Call your healthcare provider right away if you get any signs of liver problems. (see “What is the most important information I should know about EMTRIVA?”)
- **“flare-ups” of Hepatitis B Virus infection**, in which the disease suddenly returns in a worse way than before, can occur if you stop taking EMTRIVA. **Your healthcare provider will monitor your condition for several months after stopping EMTRIVA if you have both HIV and HBV infection.** EMTRIVA is not **approved** for the treatment of Hepatitis B Virus infection.

Other side effects with EMTRIVA when used with other anti-HIV medicines Include:

- Changes in body fat have been seen in some patients taking EMTRIVA and other anti-HIV medicines. These changes may include increased amount of fat in the upper back and neck (“buffalo hump”), breast, and around the main part of your body (trunk). Loss of fat from the legs, arms and face may also happen. The cause and long term health effects of these conditions are not known at this time.

The most common side effects of EMTRIVA used with other anti-HIV medicines are headache, diarrhea, nausea and rash. Skin discoloration may also happen with EMTRIVA.

There have been other side effects in patients taking EMTRIVA. However, these side effects may have been due to other medicines that patients were taking or to HIV itself. Some of these side effects can be serious.

This list of side effects is **not** complete. If you have questions about side effects, ask your healthcare provider or pharmacist. You should report any new or continuing symptoms to your healthcare provider right away. Your healthcare provider may be able to help you manage these side effects.

How do I store EMTRIVA?

- **Keep EMTRIVA and all other medicines out of reach of children.**
- Store EMTRIVA Capsules between 59 °F and 86 °F (15 °C to 30 °C).
- Store EMTRIVA Oral Solution in a refrigerator between 36 °F and 46 °F (2–8 °C). Do not freeze. Alternatively, the product may be stored at room temperature for up to 3 months and any remaining solution in the bottle must be discarded after the 3 months.
- Do not keep your medicine in places that are too hot or cold.
- Do not keep medicine that is out of date or that you no longer need. If you throw any medicines away make sure that children will not find them.

General information about EMTRIVA:

Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. Do not use EMTRIVA for a condition for which it was not prescribed. Do not give EMTRIVA to other people, even if they have the same symptoms you have. It may harm them.

This leaflet summarizes the most important information about EMTRIVA. If you would like more information, talk with your doctor. You can ask your healthcare provider or pharmacist for information about EMTRIVA that is written for health professionals. For more information, you may also call 1-800-GILEAD5.

What are the ingredients of EMTRIVA?

Active Ingredient: emtricitabine

Inactive Ingredients for EMTRIVA Capsules: crospovidone, magnesium stearate, microcrystalline cellulose, and povidone.

Inactive Ingredients for EMTRIVA Oral Solution: Cotton candy flavor, FD&C yellow No. 6, edetate disodium, methylparaben and propylparaben, sodium phosphate (monobasic), propylene glycol, water, and xylitol. Sodium hydroxide and hydrochloric acid may be used to adjust pH.

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