

Consumer Medicine Information

EMTRIVA® (emtricitabine) 200 mg Capsules

WHAT IS IN THIS LEAFLET

Read all of this leaflet carefully before you start taking this medicine.

This leaflet answers some of the common questions about EMTRIVA capsules. It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist about your medical condition or treatment. If you have further questions, please ask your doctor or your pharmacist.

Keep this leaflet with your EMTRIVA capsules. You may need to read it again.

This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

WHAT EMTRIVA CAPSULES ARE USED FOR

- EMTRIVA belongs to a group of antiviral medicines, called nucleoside reverse transcriptase inhibitors (NRTIs).

EMTRIVA is used to treat Human Immunodeficiency Virus (HIV) infection in adults and paediatric patients 12 years of age or older who weigh more than 33 kg. This medicine must

be taken in combination with other anti-HIV medicines.

- This medicine is not a cure for HIV infection. While taking EMTRIVA you may still develop infections or other illnesses associated with HIV infection.

BEFORE YOU TAKE EMTRIVA CAPSULES

When you must not take them

- If you are hypersensitive (allergic) to emtricitabine or any of the other ingredients of EMTRIVA. Read the side effects section to find out symptoms of allergy. The ingredients of EMTRIVA are listed in the product description section of this leaflet.

- Do not take EMTRIVA, if you are already taking TRUVADA (tenofovir disoproxil fumarate/emtricitabine combination tablet), ATRIPLA (tenofovir disoproxil fumarate/emtricitabine/efavirenz combination tablet), EVIPLERA (tenofovir disoproxil fumarate/emtricitabine/rilpivirine combination tablet), STRIBILD (tenofovir disoproxil fumarate/emtricitabine/elvitegravir/cobicistat), Combivir, 3TC, Zeffix, Kivexa, Trizivir or any other medications containing lamivudine.

- Do not take EMTRIVA if you are over the age of 65 before discussing this with your doctor.

- Do not use EMTRIVA to treat any other condition unless your doctor says that you should do so.

- Do not take EMTRIVA after the expiry or “use by” date (EXP) printed on the back of the pack. If you take it after the expiry date has passed, it may not work as well.

- Do not take EMTRIVA if the packaging is torn or shows signs of tampering.

- If you are not sure whether you should be taking EMTRIVA, talk to your doctor.

Before you start to take EMTRIVA

You must tell your doctor if:

- You are allergic to foods, dyes, preservatives or any other medicines.
- You are pregnant, trying to become pregnant or breast feeding.

The safe use of EMTRIVA in human pregnancy has not been demonstrated. For this reason, it is important that women of child-bearing age receiving treatment with EMTRIVA use an effective method of contraception to avoid becoming pregnant. The active substance in this medicine (emtricitabine) has been found in breast milk at low concentrations. Consequently, it is recommended that nursing mothers do not breast-feed during treatment with EMTRIVA. In general, women infected with HIV should not breast-feed their infants in order

to avoid transmission of HIV to their newborn infant.

Tell your doctor if:

occurred unless it occurs within 1 hour after taking EMTRIVA.

- You have or have ever had liver problems including hepatitis B infection.
- You have or have ever had kidney problems.

- You are taking any other medicines, including medicines you buy without a prescription from a pharmacy, supermarket or health food shop.
- Some medicines may affect the way others work. Your doctor or pharmacist will be able to tell you what to do when taking EMTRIVA with other medicines.

How long to take EMTRIVA

Because your medicine helps to control your condition, but does not cure it, you will need to take EMTRIVA every day. Do not stop taking EMTRIVA without first talking to your doctor.

If you forget to take EMTRIVA

It is important to take the prescribed daily dose in order to get the maximum benefit of treatment.

This medicine is only available from a pharmacist after it has been prescribed by a doctor who specialises in the treatment of HIV infection. If you wish to continue receiving treatment with EMTRIVA it is important you remain under the care of a hospital or doctor who specialises in the treatment of HIV infection.

HOW TO TAKE EMTRIVA

Always take the dose recommended by your doctor to ensure that your medicine is fully effective and to reduce the development of drug resistance.

If you forget to take your daily dose of EMTRIVA take it as soon as you remember. Do not take a double dose to make up for a forgotten dose. Do not take more than one dose of EMTRIVA in a day.

EMTRIVA does not reduce the risk of passing HIV to others through sexual contact or blood contamination. Therefore, it is important to continue to take appropriate precautions to prevent passing HIV to others.

How much to take

Take one EMTRIVA 200 mg capsule once daily with or without food or as advised by your doctor.

If you take too much (Overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 131126), or in New Zealand the Poisons Centre (telephone 0800 764 766) or go to the accident and emergency department at your nearest hospital if you think you or anyone else may have taken too many EMTRIVA capsules. Do this even if there are no signs of discomfort or poisoning. This may need urgent medical attention.

If you have a long standing viral infection of your liver (hepatitis B) it may flare up when you stop taking EMTRIVA. This can cause serious illness particularly if your liver is already not working very well. If you have both HIV and hepatitis B, when you start taking your EMTRIVA capsules and even after you stop, your doctor is likely to arrange tests from time to time to check how well your liver is working.

Taking other medicines

Your doctor will generally prescribe EMTRIVA in combination with a number of other anti-HIV medicines.

- If you are not sure how much EMTRIVA you should take, check with your doctor or pharmacist. Do not change the amount of EMTRIVA you take unless told to do so by your doctor.
- Your doctor will tell you how much EMTRIVA to take and how often to take them. You will also find this information on the label of your medicine container.

WHEN YOU ARE TAKING EMTRIVA CAPSULES

Things you must do

EMTRIVA is absorbed rapidly. Do not take another EMTRIVA 200 mg capsule if vomiting has

- Tell your doctor or pharmacist that you are taking EMTRIVA

if you are about to be started on any other medicines.

- Tell your doctor if you become pregnant or are trying to become pregnant.
- Tell your doctor if for any reason you have not taken your medicine exactly as prescribed.

Things you must not do

- Do not stop taking EMTRIVA capsules or change the dose without first checking with your doctor.
- Do not give this medicine to anyone else even if their symptoms seem similar to yours.
- Do not use EMTRIVA to treat any other complaints unless your doctor says to.

Things to be careful of

Be careful driving or operating machinery until you know how the EMTRIVA capsules affect you.

POSSIBLE SIDE EFFECTS

Like all medicines, EMTRIVA can have side effects. Some may be serious and need medical attention.

Check with your doctor as soon as possible if you have any problems while taking EMTRIVA, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- Headache
- Nausea
- Diarrhoea
- Muscle pain and weakness
- Dizziness
- Skin rash
- Changes in skin colour on the palms of the hands or soles of the feet
- Fatigue/Tiredness
- Difficulty sleeping
- Abnormal dreams
- Pain
- Vomiting
- Problems with digestion

Redistribution, accumulation or loss of body fat may occur in people receiving combination antiretroviral therapy. Contact your doctor if you notice changes in body fat.

Ask your doctor or pharmacist to answer any question you may have about these or other effects.

Allergy

Some people are allergic to medicines. If you have any of the following symptoms soon after taking your medicine, DO NOT TAKE ANY MORE EMTRIVA and tell your doctor IMMEDIATELY or go to the accident and emergency department at your nearest hospital:

- Skin troubles such as lumpy skin rash or “hives”
- Swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing
- Wheezing, chest pain or tightness
- Fainting

These are very serious effects. If you have them, you may have a serious allergic reaction. You may need urgent medical attention or hospitalisation. All of these side effects are very rare.

Serious Liver Problems (hepatotoxicity)

If you have any of the following symptoms after starting taking your medication DO NOT TAKE ANY MORE EMTRIVA OR OTHER ANTI-HIV MEDICINES and tell your doctor IMMEDIATELY or go to the accident and emergency department at your nearest hospital.

- Your skin or the white part of your eyes turn yellow (jaundice)
- Your urine turns dark
- Your bowel movements (stools) turn light in colour
- Nausea
- Stomach pains

These side effects may be due to a condition called hepatotoxicity with liver enlargement and fat deposits in the liver (steatosis) which sometimes occurs in patients taking anti-HIV medicines.

Lactic Acidosis

If you have any of the following symptoms after taking your medication DO NOT TAKE ANY MORE EMTRIVA OR OTHER ANTI-HIV MEDICINES and tell your doctor IMMEDIATELY or go to the accident and emergency department at your nearest hospital.

- 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 arms and legs.
- You feel dizzy or lightheaded.
- You have a fast or irregular heartbeat.

These side effects may be due to a condition called lactic acidosis (build up of an acid in the blood). Lactic acidosis can be a medical emergency and may need to be treated in the hospital.

Hepatic Flares

If you have HIV infection and chronic hepatitis B infection you should not stop your EMTRIVA treatment without first discussing this with your doctor, as some patients have had blood tests or symptoms indicating a worsening of their hepatitis (“hepatic flare”) after stopping EMTRIVA. You may require blood tests for several months after stopping treatment.

Other side effects

This list of side effects is not complete. There have been other side effects in patients taking EMTRIVA. Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

Some people may get other side effects while taking EMTRIVA. If you are concerned, talk to your doctor or pharmacist.

Ask your doctor or pharmacist if you don’t understand anything in this list.

Do not be alarmed by this list of possible side-effects. Most of them are very rare and you may not experience any of them.

AFTER TAKING EMTRIVA

Storing EMTRIVA

Keep EMTRIVA capsules where children cannot reach them. A locked cupboard at least one-and-a-half metres above the ground is a good place to store them.

Keep EMTRIVA capsules in a cool, dry place where it stays below 30°C.

Do not store EMTRIVA or any other medicine in a bathroom or near a sink.

Do not leave them in the car or on a window sill – heat and dampness can destroy some medicines.

Keep your EMTRIVA capsules in the bottle with the cap tightly closed until you take them. If you take EMTRIVA capsules out of their pack they may not keep well.

Disposal

If your doctor tells you to stop taking EMTRIVA, or the medicine has passed their expiry date, ask your pharmacist what to do with any capsules left over.

PRODUCT DESCRIPTION

What EMTRIVA capsules look like

EMTRIVA 200 mg hard capsules have a white opaque body with a light blue opaque cap. Each capsule is printed with “200 mg” on the white cap and “GILEAD” and the Gilead shield logo on the white body in black ink. EMTRIVA capsules are supplied in bottles containing 30 capsules.

EMTRIVA Capsule Ingredients

Each EMTRIVA capsule contains 200 mg emtricitabine.

Other ingredients are:

- Cellulose, microcrystalline
- Crospovidone
- Magnesium stearate
- Povidone
- Purified water
- Capsule shell
- Printing ink

TT50-7124

SPONSOR

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