

## EMTRIVA® Capsules

200 mg emtricitabine

### Consumer Medicine Information

#### What is in this leaflet

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 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.

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

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

#### How EMTRIVA works

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) may develop.

EMTRIVA helps block HIV-1 reverse transcriptase, a viral chemical in your body (enzyme) that is needed for HIV-1 to multiply. EMTRIVA lowers the amount of HIV in the blood (viral load). EMTRIVA may also help to increase the number of T cells (CD4<sup>+</sup> cells), allowing your immune system to improve. 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).

#### Before you take EMTRIVA

##### Who must not take it

**Do not take EMTRIVA if you are allergic to:**

- emtricitabine or
- any of the other ingredients of EMTRIVA.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- rash, itching or hives on the skin
- swelling of the face, lips, tongue or other parts of the body

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.

**Do not take EMTRIVA, if you are already taking any other medicines that contain the same active ingredients such as:**

- TRUVADA
- ATRIPLA
- EVIPLERA
- STRIBILD
- GENVOYA

**Do not take EMTRIVA if you are taking other medicines that contain:**

- lamivudine (e.g. Combivir, 3TC, Zeffix, Kivexa, Trizivir)

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

Do not take EMTRIVA after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

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

#### Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if 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 you have or have ever had liver problems including hepatitis B infection.

Tell your doctor if you have or have ever had kidney problems.

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.

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. 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.

Your doctor can discuss with you the benefits and risks of taking EMTRIVA.

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking EMTRIVA.

#### Taking other medicines

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

Tell your doctor or pharmacist if you are taking any other medicines including any that you buy without a prescription from your 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 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.

They may differ from the information contained in this leaflet.

**If you do not understand the instructions on the label, ask your doctor or pharmacist for help.**

#### How much to take

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

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.

EMTRIVA is absorbed rapidly. Do not take another EMTRIVA 200 mg capsule if vomiting has occurred unless it occurs within 1 hour after taking EMTRIVA.

#### How long to take it

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 it

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

**If it is almost time for your next dose, skip the dose you missed and take the next dose when you are meant to.**

**Otherwise, take it as soon as you remember, then go back to taking it as you would normally.**

**Do not take a double dose to make up for the dose that you have missed.**

This may increase the chance of you getting an unwanted side effect.

**If you are not sure what to do, ask your doctor or pharmacist.**

If you have trouble remembering to use your medicine, ask your pharmacist for some hints.

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#### If you take too much (overdose)

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**Immediately telephone your doctor, pharmacist or Poisons Information Centre 13 11 26 (Australia) and 0800 764 766 (New Zealand) or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have taken too much EMTRIVA. Do this even if there are no signs of discomfort or poisoning.**

You may need urgent medical attention.

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#### While you are taking EMTRIVA

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##### *Things you must do*

**Tell your doctor or pharmacist that you are taking EMTRIVA if you are about to be started on any other medicines.**

**If you feel that EMTRIVA is not helping your condition, tell your doctor or pharmacist.**

**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.**

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

**Tell your doctor as soon as possible if there is any worsening of your condition.**

##### *Things you must not do*

**Do not give EMTRIVA to anyone else, even if they have the same condition as you.**

**Do not stop taking EMTRIVA capsules or change the dose without first checking with your doctor.**

It is important not to suddenly stop taking your EMTRIVA capsules, unless advised to do so by your doctor, since your condition may worsen.

Do not use EMTRIVA to treat any other complaints unless your doctor says so.

##### *Things to be careful of*

**Be careful driving or operating machinery until you know how EMTRIVA affects you.**

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#### Side effects

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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.

#### **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.

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#### After taking EMTRIVA

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##### *Storage*

**Keep your EMTRIVA capsules in the bottle with the cap tightly closed until you take 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 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.

##### *Disposal*

**If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.**

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#### Product description

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##### *What it looks like*

EMTRIVA is the brand name of your medicine.

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.

##### *Ingredients*

Each EMTRIVA capsule contains 200 mg emtricitabine.

Each EMTRIVA capsule also contains the following ingredients:

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

##### *Sponsor*

#### **Australia**

Gilead Sciences Pty Ltd  
Level 6, 417 St Kilda Road  
Melbourne, Victoria 3004

#### **New Zealand**

Gilead Sciences (NZ)  
c/- PricewaterhouseCoopers  
Level 8 Pricewaterhousecoopers Tower  
188 Quay Street  
Auckland 1010  
AUST R 96426, 96427

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