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APPROVED PATIENT INFORMATION LEAFLET JULY 2025

SCHEDULING STATUS: S4

Emtritaf 200/25 200/25 mg

emtricitabine/tenofovir alafenamide

Sugar Free

WARNING:

TOO MUCH LACTIC ACID IN YOUR BLOOD (LACTIC ACIDOSIS) IS A SERIOUS BUT RARE MEDICAL EMERGENCY THAT CAN LEAD TO DEATH. TELL YOUR HEALTHCARE PROVIDER RIGHT AWAY IF YOU GET THESE SYMPTOMS: WEAKNESS OR BEING TIRED MORE THAN USUAL, UNUSUAL MUSCLE PAIN, BEING SHORT OF BREATH OR FAST BREATHING, STOMACH PAIN WITH NAUSEA AND VOMITING, COLD OR BLUE HANDS AND FEET, FEEL DIZZY OR LIGHTHEADED, OR A FAST OR ABNORMAL HEARTBEAT.

IF YOU HAVE HEPATITIS B INFECTION, YOUR DOCTOR WILL CAREFULLY CONSIDER THE BEST TREATMENT REGIMEN FOR YOU. IF YOU HAVE HEPATITIS B INFECTION, LIVER PROBLEMS MAY BECOME WORSE AFTER YOU STOP TAKING Emtritaf 200/25. IT IS IMPORTANT NOT TO STOP TAKING Emtritaf 200/25 WITHOUT TALKING TO YOUR DOCTOR. YOU MUST REMAIN UNDER THE CARE OF YOUR DOCTOR WHILE TAKING Emtritaf 200/25.

Read all of this leaflet carefully before you start taking Emtritaf 200/25

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- Emtritaf 200/25 has been prescribed for you personally and you should not share your

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medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What Emtritaf 200/25 is and what it is used for

Emtritaf 200/25 contains two active substances:

• emtricitabine, an antiretroviral medicine of a type known as a nucleoside reverse transcriptase inhibitor (NRTI)

• tenofovir alafenamide, an antiretroviral medicine of a type known as a nucleotide reverse transcriptase inhibitor (NtRTI)

Emtritaf 200/25 blocks the action of the reverse transcriptase enzyme, which is essential for the virus to multiply. **Emtritaf 200/25** therefore reduces the amount of HIV in your body.

Emtritaf 200/25 in combination with other medicines is for the treatment of human immunodeficiency virus 1 (HIV-1) infection in adults and adolescents 12 years of age and older, who weigh at least 35 kg.

2. What you need to know before you take Emtritaf 200/25

Do not take Emtritaf 200/25:

If you are allergic to emtricitabine, tenofovir alafenamide or any of the other ingredients of this

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medicine (listed in section 6 of this leaflet).

Warnings and precautions

Too much lactic acid blood (lactic in your acidosis) is a serious but rare medical emergency that can lead to death. Tell your healthcare provider right away if you get these symptoms: weakness or being more tired than usual, unusual muscle pain, being short of breath or fast breathing, stomach pain with nausea and vomiting, cold or blue hands and feet, feel dizzy or lightheaded, or a fast or abnormal heartbeat.

If you have hepatitis B infection, your doctor will carefully consider the best treatment regimen for you.
If you have hepatitis B infection, liver problems may become worse after you stop taking **Emtritaf 200/25.** It is important not to stop taking **Emtritaf 200/25** without talking to your doctor.
You must remain under the care of your doctor while taking **Emtritaf 200/25**.
You can still pass on HIV when taking **Emtritaf 200/25**. Discuss with your doctor the precautions needed to avoid infecting other people. **Emtritaf 200/25** is not a cure for HIV infection. While taking **Emtritaf 200/25** you may still develop infections or other illnesses associated with HIV infection.
During HIV therapy such as with **Emtritaf 200/25** there may be an increase in weight and in levels of blood lipids and glucose. This is partly linked to restored health and life style, and in the case of blood lipids sometimes to the HIV medicines themselves. Your doctor will test for these changes.
Autoimmune disorders (the immune system attacks healthy body tissue), may also occur after you start taking medicines for HIV infection such as **Emtritaf 200/25**. Autoimmune disorders may occur many months after the start of treatment. Look out for any symptoms of infection or other symptoms such as:

• Muscle weakness
• Weakness beginning in the hands and feet and moving up towards the trunk of the body
• Palpitations, tremor or hyperactivity

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Talk to your doctor before taking Emtritaf 200/25:

If you have liver problems or have suffered liver disease, including hepatitis.

• Patients with liver disease including chronic hepatitis B or C, who are treated with antiretrovirals, have a higher risk of severe and potentially fatal liver complications. If you have hepatitis B infection, your doctor will carefully consider the best treatment regimen for you.

• If you have hepatitis B liver problems it may become worse after you stop taking **Emtritaf 200/25**. Do not stop taking **Emtritaf 200/25** without talking to your doctor: see section 3, Do not stop taking **Emtritaf 200/25**.

• Your doctor may not prescribe **Emtritaf 200/25** to you if the virus has a K65R mutation.

Once you start taking **Emtritaf 200/25**, look out for:

• Signs of inflammation or infection

• Any signs of inflammation or infection. In some patients with advanced HIV infection (AIDS) and who have had opportunistic infections in the past (infections that occur in people with a weak immune system), signs and symptoms of inflammation from previous infections may occur soon after antiretroviral treatment, such as with **Emtritaf 200/25**, is started. It is thought that these symptoms are due to an improvement in the body's immune response, enabling the body to fight infections that may have been present with no obvious symptoms.

Joint pain, stiffness or bone problems

• Bone problems. Some patients taking combination antiretroviral medicines such as **Emtritaf 200/25** may develop a bone disease called osteonecrosis (death of bone tissue caused by loss of blood supply to the bone). Taking this type of medicine for a long time, taking corticosteroids, drinking alcohol, having a very weak immune system, and being overweight, may be some of the many risk factors for developing this disease. Signs of osteonecrosis are:

- Joint stiffness
- Joint aches and pains (especially of the hip, knee and shoulder)
- Difficulty with movement

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If you notice any of these symptoms, tell your doctor immediately. For more information see section 4, Possible side effects.

Although kidney problems have not been observed with **Emtritaf 200/25**, there is a possibility that you may experience kidney problems when taking **Emtritaf 200/25** over a long period of time.

Use in children and adolescents

Do not give this medicine to children under 12 years of age, or weighing less than 35 kg. The use of **Emtritaf 200/25** in children under 12 years of age has not been studied.

Other medicines and Emtritaf 200/25

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

Medicines used in treating hepatitis B infection:

You should not take **Emtritaf 200/25** with medicines containing:

• Tenofovir alafenamide

• Tenofovir disoproxil

• Lamivudine

• Adefovir dipivoxil

Tell your doctor if you are taking any of these medicines.

Other types of medicine:

Talk to your doctor if you are taking:

- Antibiotics, used to treat bacterial infections including tuberculosis, containing: rifabutin, rifampicin, and rifapentine

antiviral medicines used to treat HIV: emtricitabine and tipranavir

anticonvulsants, used to treat epilepsy, such as: carbamazepine, oxcarbazepine, phenobarbitone and phenytoin

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herbal remedies used to treat depression and anxiety containing:

- St. John's wort (*Hypericum perforatum*)

Tell your doctor if you are taking these or any other medicines. Do not stop your treatment without contacting your doctor.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking **Emtritaf 200/25**.

Use effective contraception while taking **Emtritaf 200/25**.

Ask your doctor or pharmacist for advice before taking any medicine when pregnant.

If you have taken **Emtritaf 200/25** during your pregnancy, your doctor may request regular blood tests and other diagnostic tests to monitor the development of your child. In children whose mothers took NRTIs during pregnancy, the benefit from the protection against HIV outweighed the risk of side effects.

Do not breast-feed your baby during treatment with **Emtritaf 200/25**.

One of the active substances in **Emtritaf 200/25** (emtricitabine) passes into breast milk and possible harm to your baby cannot be excluded.

It is also recommended that you do not breast-feed your baby to avoid passing the HIV virus to the baby through your breast milk.

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Driving and using machines

Emtritaf 200/25 may affect your ability to drive and use machines. Do not drive and use machines until you know how treatment with **Emtritaf 200/25** affects you.

3. How to take Emtritaf 200/25

Do not share medicines prescribed for you with any other person.

Always take **Emtritaf 200/25** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are not sure.

The recommended dose is:

Adults: one tablet each day, with or without food

Adolescents 12 years of age and older, who weigh at least 35 kg: one tablet each day with or without food

Do not chew, crush or split the tablet.

Always take the dose recommended by your doctor. This is to make sure that your medicine is fully effective, and to reduce the risk of developing resistance to the treatment. Do not change the dose unless your doctor tells you to.

If you are on dialysis, take your daily dose of **Emtritaf 200/25** following completion of dialysis.

If you have the impression that the effect of **Emtritaf 200/25** is too strong or too weak, talk to your doctor or pharmacist.

If you take more Emtritaf 200/25 than you should

In the event of over dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

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If you forget to take Emtritaf 200/25

It is important to take your **Emtritaf 200/25** regularly at the same time each day.

It is important not to miss a dose of **Emtritaf 200/25**.

If you do miss a dose:

If you notice within 18 hours of the time you usually take **Emtritaf 200/25**, you must take the tablet as soon as possible. Then take the next dose as usual.

If you notice 18 hours or more after the time you usually take **Emtritaf 200/25**, then do not take the missed dose. Wait and take the next dose at your usual time.

If you vomit less than 1 hour after taking **Emtritaf 200/25**, take another tablet.

Do not stop taking Emtritaf 200/25

4 Possible side effects

Emtritaf 200/25 can have side effects.

Not all side effects reported for **Emtritaf 200/25** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **Emtritaf 200/25**, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking **Emtritaf 200/25** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Any signs of inflammation or infection. In some patients with advanced HIV infection (AIDS) and who have had opportunistic infections in the past (infections that occur in people with a weak immune system), signs and symptoms of inflammation from previous infections may occur soon after antiretroviral treatment such as with **Emtritaf 200/25** is started. It is thought that these symptoms are due to an improvement in the body's

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immune response, enabling the body to fight infections that may have been present with no obvious symptoms.

- Autoimmune disorders (the immune system attacks healthy body tissue), may also occur after you start taking medicines for HIV infection such as **Emtritaf 200/25**. Autoimmune disorders may occur many months after the start of treatment. Look out for any symptoms of infection or other symptoms such as:
  - muscle weakness
  - weakness beginning in the hands and feet and moving up towards the trunk of the body
  - palpitations, tremor or hyperactivity

If you notice the side effects described above, tell your doctor immediately.

- Swelling of the face, lips or throat with difficult breathing (angioedema)

These are all very serious side effects. If you have them, you may have had a serious reaction to **Emtritaf 200/25**. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent

- Feeling sick (nausea)
- Abnormal dreams
- Headache
- Dizziness
- Diarrhoea
- Vomiting
- Stomach pain
- Wind (flatulence)
- Rash

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- Tiredness (fatigue)

Less frequent:

- Itching (pruritus),
- Hives (urticaria)
- Low red blood cell count (anaemia)
- Problems with digestion resulting in discomfort after meals (dyspepsia)
- Joint pain (arthralgia)

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Should your general health worsen or if you experience any untoward effects while taking **Emtritaf 200/25**, please consult your healthcare provider for advice.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website or to Macleods Pharmaceuticals SA (Pty) Ltd. at safety@macleodspharma.com. By reporting side effects, you can help provide more information on the safety of **Emtritaf 200/25.**

5. How to store Emtritaf 200/25

Store at or below 25 °C.

KEEP OUT OF THE REACH OF CHILDREN.

Store in the original package / container.

Keep the HDPE container tightly closed.

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Do not store in a bathroom.

Do not use after the expiry date stated on the blister / label / carton bottle.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of pack and other information

What Emtritaf 200/25 contains

The active ingredients are emtricitabine and tenofovir alafenamide.

The other ingredients are:

Tablet Core:

Microcrystalline Cellulose

Croscarmellose Sodium

Magnesium Stearate

Tablet Coat:

Opadry White, Isopropyl Alcohol and Methylene Chloride

Opadry White: HPMC /Hypromellose, Titanium dioxide, Macrogol/PEG, Talc

What Emtritaf 200/25 looks like and contents of the pack

Emtritaf 200/25 200/25 mg: White to off-white, oval shaped, film coated tablets, debossed with 'J57' on one side and plain on other side.

Contents of the pack:

Round, white, HDPE container with neck finish, containing tablets and silica gel sachets, closed with child resistant closure with pulp and heat seal liner and packed in a pre-printed unit carton.

Pack sizes include 28’s and 30’s tablets.

Not all pack sizes may be marketed.

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7. HOLDER OF CERTIFICATE OF REGISTRATION

MACLEODS PHARMACEUTICALS SA (PTY) LTD

GROUND FLOOR, BLOCK 1,

BASSONIA ESTATE OFFICE PARK (EAST),

1 CUSSONIA DRIVE,

BASSONIA ROCK EXT 12

ALBERTON

GAUTENG

This leaflet was last revised in

08 July 2025

Registration number

58/20.2.8/0027.026

Access to the corresponding Professional Information

The corresponding professional information can be accessed at https://www.macleodspharma.com or email macleodsrsa@macleodspharma.com or contact 011 682 1169

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