Package leaflet: Information for the user

Emtricitabine/Tenofoviralafenamide Lupin 200 mg/25 mg filmomhulde tabletten
emtricitabine/tenofoviralafenamide

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Emtricitabine/Tenofoviralafenamide Lupin is and what it is used for

Emtricitabine/Tenofoviralafenamide Lupin 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)

Emtricitabine/Tenofoviralafenamide Lupin blocks the action of the reverse transcriptase enzyme, which is essential for the virus to multiply. Emtricitabine/Tenofoviralafenamide Lupin, therefore, reduces the amount of HIV in your body.

Emtricitabine/Tenofoviralafenamide Lupin 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 Emtricitabine/Tenofoviralafenamide Lupin

Do not take Emtricitabine/Tenofoviralafenamide Lupin
- **If you are allergic to emtricitabine, tenofovir alafenamide** or any of the other ingredients of this medicine (listed in section 6 of this leaflet).

Warnings and precautions

You must remain under the care of your doctor while taking Emtricitabine/Tenofoviralafenamide Lupin.

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

Talk to your doctor before taking Emtricitabine/Tenofoviralafenamide Lupin:

- **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 infection, liver problems may become worse after you stop taking Emtricitabine/Tenofoviralafenamide Lupin. Do not stop taking Emtricitabine/Tenofoviralafenamide Lupin without talking to your doctor: see section 3, *Do not stop taking Emtricitabine/Tenofoviralafenamide Lupin*.

- Your doctor may choose to not prescribe Emtricitabine/Tenofoviralafenamide Lupin to you if your virus has a certain resistance mutation, as Emtricitabine/Tenofoviralafenamide Lupin may not be able to reduce the amount of HIV in your body as effectively.

- **If you have had kidney disease or if tests have shown problems with your kidneys.** Your doctor may order blood tests to monitor how your kidneys work when starting and during treatment with Emtricitabine/Tenofoviralafenamide Lupin.

While you are taking Emtricitabine/Tenofoviralafenamide Lupin

Once you start taking Emtricitabine/Tenofoviralafenamide Lupin, look out for:

- **Signs of inflammation or infection**
- **Joint pain, stiffness** or **bone problems**

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

There is a possibility that you may experience kidney problems when taking Emtricitabine/Tenofoviralafenamide Lupin over a long period of time (see *Warnings and precautions)*.

Children and adolescents

Do not give this medicine to children aged 11 years or under, or weighing less than 35 kg. The use of Emtricitabine/Tenofoviralafenamide Lupin in children aged 11 years or under has not yet been studied.

Other medicines and Emtricitabine/Tenofoviralafenamide Lupin

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Emtricitabine/Tenofoviralafenamide Lupin may interact with other medicines. As a result, the amounts of Emtricitabine/Tenofoviralafenamide Lupin or other medicines in your blood may change. This may stop your medicines from working properly, or may make any side effects worse. In some cases, your doctor may need to adjust your dose or check your blood levels.

Medicines used in treating hepatitis B infection:
You should not take Emtricitabine/Tenofoviralafenamide Lupin 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, phenobarbital and phenytoin
- **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 and breast-feeding

- If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
- Tell your doctor immediately if you become pregnant and ask about the potential benefits and risks of your antiretroviral therapy to you and your child.

If you have taken Emtricitabine/Tenofoviralafenamide Lupin 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 during treatment with Emtricitabine/Tenofoviralafenamide Lupin. This is because one of the active substances in this medicine passes into breast milk.

Breast-feeding is not recommended in women living with HIV because HIV infection can be passed on to the baby in breast milk.

If you are breast-feeding, or thinking about breast-feeding, you should **discuss it with your doctor as soon as possible**.

Driving and using machines
Emtricitabine/Tenofoviralafenamide Lupin can cause dizziness. If you feel dizzy when taking Emtricitabine/Tenofoviralafenamide Lupin, do not drive and do not use any tools or machines.

Emtricitabine/Tenofoviralafenamide Lupin contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

Emtricitabine/Tenofoviralafenamide Lupin contains lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Emtricitabine/Tenofoviralafenamide Lupin

Always take this medicine exactly as your doctor has told you. 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

It is recommended not to chew or crush the tablet due to the bitter taste.

If you have difficulty swallowing the tablet whole, you can split it in half. Take both halves of the tablet one after the other to get the full dose. Do not store the split 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 Emtricitabine/Tenofoviralafenamide Lupin following completion of dialysis.

If you take more Emtricitabine/Tenofoviralafenamide Lupin than you should

If you take more than the recommended dose of Emtricitabine/Tenofoviralafenamide Lupin you may be at higher risk of side effects of this medicine (see section 4, *Possible side effects*).

Contact your doctor or nearest emergency department immediately for advice. Keep the tablet bottle with you so that you can show what you have taken.

If you forget to take Emtricitabine/Tenofoviralafenamide Lupin

It is important not to miss a dose of Emtricitabine/Tenofoviralafenamide Lupin.

If you do miss a dose:
- **If you notice within 18 hours** of the time you usually take Emtricitabine/Tenofoviralafenamide Lupin, 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 Emtricitabine/Tenofoviralafenamide Lupin, 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 Emtricitabine/Tenofoviralafenamide Lupin, take another tablet.

Do not stop taking Emtricitabine/Tenofoviralafenamide Lupin

Do not stop taking Emtricitabine/Tenofoviralafenamide Lupin without talking to your doctor. Stopping Emtricitabine/Tenofoviralafenamide Lupin can seriously affect how well future treatment works. If Emtricitabine/Tenofoviralafenamide Lupin is stopped for any reason, speak to your doctor before you restart taking Emtricitabine/Tenofoviralafenamide Lupin tablets.

When your supply of Emtricitabine/Tenofoviralafenamide Lupin starts to run low, get more from your doctor or pharmacist. This is very important because the amount of virus may start to increase if the medicine is stopped for even a few days. The disease may then become harder to treat.

If you have both HIV infection and hepatitis B, it is very important not to stop taking Emtricitabine/Tenofoviralafenamide Lupin without talking to your doctor first. You may require blood tests for several months after stopping treatment. In some patients with advanced liver disease or cirrhosis, stopping treatment may lead to worsening of hepatitis, which may be life-threatening.

➔ **Tell your doctor immediately** about new or unusual symptoms after you stop treatment, particularly symptoms you associate with hepatitis B infection.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Possible serious side effects: tell a doctor immediately

- **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 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.
- **Autoimmune disorders** (the immune system attacks healthy body tissue), may also occur after you start taking medicines for HIV infection. 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.**

Very common side effects
(*may affect more than 1 in 10 people*)
- feeling sick (*nausea*)

Common side effects
(*may affect up to 1 in 10 people*)
- abnormal dreams
- headache
- dizziness
- diarrhoea
- vomiting
- stomach pain
- wind (*flatulence*)
- rash
- tiredness (*fatigue*)

Uncommon side effects
(*may affect up to 1 in 100 people*)
- low red blood cell count (*anaemia*)
- problems with digestion resulting in discomfort after meals (*dyspepsia*)
- swelling of the face, lips, tongue or throat (*angioedema*)
- itching (*pruritus*)
- hives *(urticaria)*
- joint pain *(arthralgia)*

➔ **If any of the side effects get serious tell your doctor.**

Other effects that may be seen during HIV treatment

The frequency of the following side effects is not known (frequency cannot be estimated from the available data).

- **Bone problems.** Some patients taking combination antiretroviral medicines such as Emtricitabine/Tenofoviralafenamide Lupin 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

➔ **If you notice any of these symptoms tell your doctor.**

During HIV therapy there may be an increase in weight and in levels of blood lipids and glucose. This is partly linked to restored health and lifestyle, and in the case of blood lipids sometimes to the HIV medicines themselves. Your doctor will test for these changes.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Nederlands Bijwerkingen Centrum Lareb Website: www.lareb.nl.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Emtricitabine/Tenofoviralafenamide Lupin

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and bottle after “EXP”. The expiry date refers to the last day of that month.

This medicinal product does not require any special temperature storage conditions. Store in the original package in order to protect from moisture. Keep the bottle tightly closed. Do not remove the desiccant. Do not swallow the desiccant.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Emtricitabine/Tenofoviralafenamide Lupin contains

The active substances are emtricitabine and tenofovir alafenamide. Each Emtricitabine/Tenofoviralafenamide Lupin film-coated tablet contains 200 mg of emtricitabine and tenofovir alafenamide succinate equivalent to 25 mg of tenofovir alafenamide.

The other ingredients are

Tablet core:
Microcrystalline cellulose, sodium stearyl fumarate, croscarmellose sodium, magnesium stearate, lactose anhydrous.

Film-coating:
Hydroxypropyl cellulose, hypromellose, talc, calcium carbonate.

What Emtricitabine/Tenofoviralafenamide Lupin looks like and contents of the pack

Emtricitabine/Tenofoviralafenamide Lupin are white to off white coloured, capsule shaped, film-coated tablets debossed with 'L' on one side and '0' on the other side.

Emtricitabine/Tenofoviralafenamide Lupin comes in bottles of 30 tablets (with molecular sieve desiccant that must be kept in the bottle to help protect your tablets). The molecular sieve desiccant should not be swallowed.

The following pack sizes are available: Outer cartons containing 1 bottle of 30 film-coated tablets and outer cartons containing 60 (2 bottles of 30) and 90 (3 bottles of 30) film-coated tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder:
Lupin Europe GmbH
Hanauer Landstrasse 139-143,
60314 Frankfurt Am Main,
Duitsland

Manufacturer:
Hormosan Pharma GmbH
Hanauer Landstrasse 139-143,
60314 Frankfurt Am Main,
Duitsland

In het register ingeschreven onder:
RVG 134777

Deze bijsluiter is voor het laatst goedgekeurd in augustus 2026.