Package leaflet: Information for the user

Emtricitabin/Tenofovirdisoproxil 200 mg/245 mg film-coated tablets
emtricitabine/tenofovir disoproxil

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 Emtricitabin/Tenofovirdisoproxil is and what it is used for
2. What you need to know before you take Emtricitabin/Tenofovirdisoproxil
3. How to take Emtricitabin/Tenofovirdisoproxil
4. Possible side effects
5. How to store Emtricitabin/Tenofovirdisoproxil
6. Contents of the pack and other information

1. What Emtricitabin/Tenofovirdisoproxil is and what it is used for

Emtricitabin/Tenofovirdisoproxil contains two active substances, *emtricitabine* and *tenofovir disoproxil*. Both of these active substances are *antiretroviral* medicines which are used to treat HIV infection. Emtricitabine is a *nucleoside reverse transcriptase inhibitor* and tenofovir is a *nucleotide reverse transcriptase inhibitor*. However, both are generally known as NRTIs and they work by interfering with the normal working of an enzyme (reverse transcriptase) that is essential for the virus to reproduce itself.

- **Emtricitabin/Tenofovirdisoproxil is used to treat Human Immunodeficiency Virus 1 (HIV-1) infection in adults.**
- **It is also used to treat HIV in adolescents aged 12 to less than 18 years who weigh at least 35 kg,** and who have already been treated with other HIV medicines that are no longer effective or have caused side effects.
  - This medicine should always be used combined with other medicines to treat HIV infection.
  - This medicine can be administered in place of emtricitabine and tenofovir disoproxil used separately at the same doses.

This medicine is not a cure for HIV infection. While taking this medicine you may still develop infections or other illnesses associated with HIV infection.
- **Emtricitabin/Tenofovirdisoproxil is also used to reduce the risk of getting HIV-1 infection in adults, and adolescents aged 12 years to less than 18 years who weigh at least 35 kg,** when taken daily, together with safer sex practices:
  See section 2 for a list of precautions to take against HIV infection.

2. What you need to know before you take Emtricitabin/Tenofovirdisoproxil

Do not take Emtricitabin/Tenofovirdisoproxil to treat HIV or to reduce the risk of getting HIV
if you are allergic to emtricitabine, tenofovir, tenofovir disoproxil or any of the other ingredients of this medicine (listed in section 6).

⟶ **If this applies to you, tell your doctor immediately.**

Before taking Emtricitabin/Tenofovirdisoproxil to reduce the risk of getting HIV:
Emtricitabin/Tenofovirdisoproxil can only help reduce your risk of getting HIV **before** you are infected.

- **You must be HIV negative before you start to take emtricitabine/tenofovirdisoproxil to reduce the risk of getting HIV.** You must get tested to make sure that you do not already have HIV infection. Do not take emtricitabine/tenofovirdisoproxil to reduce your risk unless you are confirmed to be HIV negative. People who do have HIV must take emtricitabine/tenofovirdisoproxil in combination with other drugs.

- **Many HIV tests can miss a recent infection**. If you get a flu-like illness, it could mean you have recently been infected with HIV.
  These may be signs of HIV infection:
  - tiredness
  - fever
  - joint or muscle aches
  - headache
  - vomiting or diarrhoea
  - rash
  - night sweats
  - enlarged lymph nodes in the neck or groin

⟶ Tell your doctor about any flu-like illness – either in the month before starting Emtricitabin/Tenofovirdisoproxil, or at any time while taking this medicine.

Warnings and precautions
While taking Emtricitabin/Tenofovirdisoproxil to reduce the risk of getting HIV:

- Take Emtricitabin/Tenofovirdisoproxil every day **to reduce your risk, not just when you think you have been at risk of HIV infection.** Do not miss any doses of Emtricitabin/Tenofovirdisoproxil, or stop taking it. Missing doses may increase your risk of getting HIV infection.

- Get tested for HIV regularly.

- If you think you were infected with HIV, tell your doctor straight away. They may want to do more tests to make sure you are still HIV negative.

- **Just taking Emtricitabin/Tenofovirdisoproxil may not stop you getting HIV.**
  - Always practice safer sex. Use condoms to reduce contact with semen, vaginal fluids, or blood.
  - Do not share personal items that can have blood or body fluids on them, such as toothbrushes and razor blades.
  - Do not share or re-use needles or other injection or drug equipment.
  - Get tested for other sexually transmitted infections such as syphilis and gonorrhoea.

These infections make it easier for HIV to infect you.

Ask your doctor if you have any more questions about how to prevent getting HIV or spreading HIV to other people.

While taking Emtricitabin/Tenofovirdisoproxil to treat HIV or to reduce the risk of getting HIV:

- **Emtricitabine/tenofovirdisoproxil may affect your kidneys.** Before and during treatment, your doctor may order blood tests to measure kidney function. Tell your doctor if you have had kidney disease, or if tests have shown kidney problems. This medicine should not be given to adolescents with existing kidney problems. If you have kidney problems, your doctor may advise you to stop taking this medicine or, if you already have HIV, to take it less frequently. The use of emtricitabine/tenofovirdisoproxil is not recommended if you have severe kidney disease or are on dialysis.

- **Talk to your doctor if you suffer from osteoporosis, have a history of bone fracture or if you have problems with your bones.**

- **Bone *problems*** (manifesting as persistent or worsening bone pain and sometimes resulting in fractures) may also occur due to damage to kidney tubule cells (see section 4, *Possible side effects).* Tell your doctor if you have bone pain or fractures.

Tenofovir disoproxil may also cause loss of bone mass. The most pronounced bone loss was seen in clinical studies when patients were treated for HIV with tenofovir disoproxil in combination with a boosted protease inhibitor.

Overall, the effects of tenofovir disoproxil on long term bone health and future fracture risk in adult and paediatric patients are uncertain.

- **Talk to your doctor if you have a history of liver disease, including hepatitis.** Patients infected with HIV who also have 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 or C, your doctor will carefully consider the best treatment regimen for you.
- **Know your hepatitis B virus (HBV) infection status** before starting this medicine. If you have HBV, there is a serious risk of liver problems when you stop taking this medicine, whether or not you also have HIV. It is important not to stop taking Emtricitabin/Tenofovirdisoproxil without talking to your doctor: see section 3, Do not stop taking Emtricitabin/Tenofovirdisoproxil.
- **Talk to your doctor if you are over 65.** Emtricitabin/Tenofovirdisoproxil has not been studied in patients over 65 years of age.
- **Talk to your doctor if you are intolerant to lactose** (see Emtricitabin/Tenofovirdisoproxil contains lactose later in this section).

Children and adolescents
Emtricitabin/Tenofovirdisoproxil is not for use in children under 12 years of age.

Other medicines and Emtricitabin/Tenofovirdisoproxil
Do not take this medicine if you are already taking other medicines that contain the components of this medicine (emtricitabine and tenofovir disoproxil) or any other antiviral medicines that contain tenofovir alafenamide, lamivudine or adefovir dipivoxil.

Taking this medicine with other medicines that can damage your kidneys: it is especially important to tell your doctor if you are taking any of these medicines , including

- aminoglycosides (for bacterial infection)
- amphotericin B (for fungal infection)
- foscarnet (for viral infection)
- ganciclovir (for viral infection)
- pentamidine (for infections)
- vancomycin (for bacterial infection)

- interleukin-2 (to treat cancer)
- cidofovir (for viral infection)
- non-steroidal anti-inflammatory drugs (NSAIDs, to relieve bone or muscle pains)

If you are taking another antiviral medicine called a protease inhibitor to treat HIV, your doctor may order blood tests to closely monitor your kidney function.

It is also important to tell your doctor if you are taking ledipasvir/sofosbuvir, sofosbuvir/velpatasvir or sofosbuvir/velpatasvir/voxilaprevir to treat hepatitis C infection.

Taking Emtricitabin/Tenofovirdisoproxil with other medicines containing didanosine (for treatment of HIV infection): Taking this medicine with other antiviral medicines that contain didanosine can raise the levels of didanosine in your blood and may reduce CD4 cell counts. Rarely, inflammation of the pancreas and lactic acidosis (excess lactic acid in the blood), which sometimes causes death, have been reported when medicines containing tenofovir disoproxil and didanosine were taken together. Your doctor will carefully consider whether to treat you with combinations of tenofovir and didanosine.

⟶ Tell your doctor if you are taking any of these medicines. Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Emtricitabin/Tenofovirdisoproxil with food and drink
- Whenever possible, this medicine should be taken with food.

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.

If you have taken this medicine 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 this medicine.** This is because the active substances in this medicine pass into human 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
Emtricitabin/Tenofovirdisoproxil can cause dizziness. If you feel dizzy while taking this medicine, **do not drive** and do not use any tools or machines.

Emtricitabin/Tenofovirdisoproxil 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.

Emtricitabin/Tenofovirdisoproxil contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per film-coated tablet, that is to say essentially ‘sodium-free’.

3. How to take Emtricitabin/Tenofovirdisoproxil

- **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 of Emtricitabin/Tenofovirdisoproxil to treat HIV is:
- **Adults:** one tablet each day, where possible, with food.
- **Adolescents aged 12 to less than 18 years who weigh at least 35 kg:** one tablet each day, whenever possible with food.

The recommended dose of Emtricitabin/Tenofovirdisoproxil to reduce the risk of getting HIV is:

Adults: one tablet each day, whenever possible, with food.
Adolescents aged 12 to less than 18 years who weigh at least 35 kg: one tablet each day, whenever possible with food.

If you have difficulty swallowing, you can use the tip of a spoon to crush the tablet. Then mix the powder with about 100 mL (half a glass) of water, orange juice or grape juice, and drink immediately.

- **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 being treated for HIV infection** your doctor will prescribe Emtricitabin/Tenofovirdisoproxil with other antiretroviral medicines. Please refer to the patient information leaflets of the other antiretrovirals for guidance on how to take those medicines.

- **If you are taking Emtricitabin/Tenofovirdisoproxil to reduce the risk of getting HIV,** take this medicine every day, not just when you think you have been at risk of HIV infection.

Ask your doctor if you have any questions about how to prevent getting HIV or prevent spreading HIV to other people.

If you take more Emtricitabin/Tenofovirdisoproxil than you should
If you accidentally take more than the recommended dose of this medicine, contact your doctor or nearest emergency department for advice. Keep the tablet bottle with you so that you can easily describe what you have taken.

If you miss a dose
It is important not to miss a dose of Emtricitabin/Tenofovirdisoproxil.

- **If you notice within 12 hours** of the time you usually take this medicine, take the tablet preferably with food as soon as possible. Then take the next dose at your usual time.

- **If you notice 12 hours or more after** the time you usually take this medicine, forget about the missed dose. Wait and take the next dose, preferably with food, at your usual time.

If you vomit less than 1 hour after taking this medicine, take another tablet. You do not need to take another tablet if you were sick more than 1 hour after taking this medicine.

Do not stop taking Emtricitabin/Tenofovirdisoproxil

- **If you take this medicine for treatment of HIV infection,** stopping tablets may reduce the effectiveness of the anti-HIV therapy recommended by your doctor.

- **If you are taking this medicine to reduce the risk of getting HIV,** do not stop taking it or miss any doses. Stopping use of this medicine, or missing doses, may increase your risk of getting HIV infection.

→ **Do not stop taking this medicine without contacting your doctor.**

- **If you have hepatitis B,** it is especially important not to stop your treatment 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 is not recommended as this may lead to worsening of your 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:
- Lactic acidosis (excess lactic acid in the blood) is a rare but potentially life-threatening side effect. Lactic acidosis occurs more often in women, particularly if they are overweight, and in people with liver disease. The following may be signs of lactic acidosis:
  - deep rapid breathing
  - drowsiness
  - feeling sick (nausea), being sick (vomiting)
  - stomach pain

→ **If you think you may have lactic acidosis, get medical help immediately.**

- **Any signs of inflammation or infection.** In some patients with advanced HIV infection (AIDS) and a history of opportunistic infections (infections that occur in people with a weak immune system), signs and symptoms of inflammation from previous infections may occur soon after anti-HIV 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,** when the immune system attacks healthy body tissue, may also occur after you start taking medicines to treat 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 these or any symptoms of inflammation or infection, get medical help immediately.**

Possible side effects:

Very common side effects *(may affect more than 1 in 10 people)*
- diarrhoea, being sick (vomiting), feeling sick (nausea)
- dizziness, headache
- rash
- feeling weak

Tests may also show:
- decreases in phosphate in the blood
- increased creatine kinase

Common side effects *(may affect up to 1 in 10 people)*
- pain, stomach pain
- difficulty sleeping, abnormal dreams
- problems with digestion resulting in discomfort after meals, feeling bloated, flatulence
- rashes (including red spots or blotches sometimes with blistering and swelling of the skin), which may be allergic reactions, itching, changes in skin colour including darkening of the skin in patches
- other allergic reactions, such as wheezing, swelling or feeling light-headed
- loss of bone mass

Tests may also show:
- low white blood cell count (a reduced white blood cell count can make you more prone to infection)
- increased triglycerides (fatty acids), bile or sugar in the blood
- liver and pancreas problems

Uncommon side effects *(may affect up to 1 in 100 people)*
- pain in the abdomen (tummy) caused by inflammation of the pancreas
- swelling of the face, lips, tongue or throat
- anaemia (low red blood cell count)
- breakdown of muscle, muscle pain or weakness which may occur due to damage to the kidney tubule cells

Tests may also show:
- decreases in potassium in the blood
- increased creatinine in your blood
- changes to your urine

Rare side effects *(may affect up to 1 in 1,000 people)*
- Lactic acidosis (see Possible serious side effects)
- fatty liver
- yellow skin or eyes, itching, or pain in the abdomen (tummy) caused by inflammation of the liver
- inflammation of the kidney, passing a lot of urine and feeling thirsty, kidney failure, damage to kidney tubule cells
- softening of the bones (with bone pain and sometimes resulting in fractures)
- back pain caused by kidney problems

Damage to kidney tubule cells may be associated with breakdown of muscle, softening of the bones (with bone pain and sometimes resulting in fractures), muscle pain, muscle weakness and decreases in potassium or phosphate in the blood.

→ **If you notice any of the side effects listed above or if any of the side effects get serious,** talk to your doctor or pharmacist.

The frequency of the following side effects is not known.

- **Bone problems.** Some patients taking combination antiretroviral medicines such as Emtricitabin/Tenofovirdisoproxil 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 treatment for HIV 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.

Other effects in children

- Children given emtricitabine very commonly experienced changes in skin colour including
  - darkening of the skin in patches
- Children commonly experienced low red blood cell count (anaemia).
  - this may cause the child to be tired or breathless

→ If you notice any of these symptoms tell your doctor.

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 the Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard or search for MHRA yellow card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Emtricitabin/Tenofovirdisoproxil

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, blister and bottle after EXP. The expiry date refers to the last day of that month.

OPA-Alu-PVC/Alu Blister: Store below 30ºC
Bottle: Store in the original package in order to protect from moisture

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 Emtricitabin/Tenofovirdisoproxil contains

- **The active substances are** emtricitabine and tenofovir disoproxil. Each film-coated tablet contains 200 mg of emtricitabine and 245 mg of tenofovir disoproxil (equivalent to 300 mg of tenofovir disoproxil fumarate or 136 mg of tenofovir).

- **The other ingredients are:**
  Tablet core: croscarmellose sodium, lactose monohydrate, cellulose, microcrystalline, magnesium stearate, starch, pregelatinised
  Tablet coating: hypromellose, lactose monohydrate, titanium dioxide (E171), triacetin, indigo carmine aluminium lake (E132)

What Emtricitabin/Tenofovirdisoproxil looks like and contents of the pack
Emtricitabin/Tenofovirdisoproxil are blue, capsule shaped, film-coated tablets debossed with 'H' on one side and 'E44' on the other side.

Pack size of 30, 60, and 90 tablets in OPA-Alu-PVC/Alu blister pack. Also available in pack size of 30x1, 60x1 and 90x1 tablets in OPA-Alu-PVC/Alu perforated unit dose blister.

Pack size of 30 tablets and 90 tablets (3 bottles of 30 tablets) in white opaque high density polyethylene (HDPE) bottle with white opaque polypropylene child-resistant closure and silica gel desiccant filled in cylindrical canister. Each bottle contains a silica gel desiccant filled in cylindrical canister that must be kept in the bottle to help protect your tablets and it should not be swallowed.

Not all pack sizes may be marketed.

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This leaflet was last revised in 02/2026.