Package leaflet: Information for the patient

Tenofovir 245 mg film-coated tablets

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

If Tenofovir 245 mg film-coated tablets has been prescribed for your child, please note that all the information in this leaflet is addressed to your child (in this case please read "your child" instead of "you").

1. What Tenofovir 245 mg film-coated tablets are and what they are used for

Tenofovir 245 mg film-coated tablets contain the active substance *tenofovir disoproxil*. This active substance is an *antiretroviral* or antiviral medicine which is used to treat HIV or HBV infection or both. Tenofovir is a *nucleotide reverse transcriptase inhibitor*, generally known as an NRTI and works by interfering with the normal working of enzymes (in HIV *reverse transcriptase*; in hepatitis B *DNA polymerase*) that are essential for the viruses to reproduce themselves. In HIV, tenofovir should always be used combined with other medicines to treat HIV infection.

Tenofovir 245 mg tablets are a treatment for HIV (Human Immunodeficiency Virus) infection. The tablets are suitable for:
- **adults**
- **adolescents aged 12 to less than 18 years who have already been treated** with other HIV medicines which are no longer fully effective due to development of resistance, or have caused side effects.

Tenofovir 245 mg tablets are also a treatment for chronic hepatitis B, an infection with HBV (hepatitis B virus). The tablets are suitable for:
- **adults**
- **adolescents aged 12 to less than 18 years.**

You do not have to have HIV to be treated with tenofovir for HBV.

This medicine is not a cure for HIV infection. While taking Tenofovir 245 mg film-coated tablets you may still develop infections or other illnesses associated with HIV infection. You can also pass on HBV to others, so it is important to take precautions to avoid infecting other people.

2. What you need to know before you take Tenofovir 245 mg film-coated tablets

DO NOT take Tenofovir 245 mg film-coated tablets
- **If you are allergic** to tenofovir, tenofovir disoproxil succinate or any of the other ingredients of this medicine (listed in section 6).

  → If this applies to you, **tell your doctor immediately and don't take Tenofovir 245 mg film-coated tablets.**

Warnings and precautions
Talk to your doctor or pharmacist before taking Tenofovir 245 mg film-coated tablets.

- Tenofovir 245 mg film-coated tablets do not reduce the risk of passing on HBV to others through sexual contact or blood contamination. You must continue to take precautions to avoid this.
- **Talk to your doctor or pharmacist if you have had kidney disease or if tests have shown problems with your kidneys.** Tenofovir 245 mg film-coated tablets should not be given to adolescents with existing kidney problems. Before starting treatment, your doctor may order blood tests to assess your kidney function. Tenofovir 245 mg film-coated tablets may affect your kidneys during treatment. Your doctor may order blood tests during treatment to monitor how your kidneys work. If you are an adult, your doctor may advise you to take the tablets less often. Do not reduce the prescribed dose, unless your doctor has told you to do so.

  Tenofovir 245 mg film-coated tablets are not usually taken with other medicines that can damage your kidneys (see *Other medicines and Tenofovir 245 mg film-coated tablets*). If this is unavoidable, your doctor will monitor your kidney function once a week.
- **Bone problems.** Some adult patients with HIV taking combination antiretroviral therapy may develop a bone disease called osteonecrosis (death of bone tissue caused by loss of blood supply to the bone). The length of combination antiretroviral therapy, corticosteroid use, alcohol consumption, severe immunosuppression, higher body mass index, among others, may be some of the many risk factors for developing this disease. Signs of osteonecrosis are joint stiffness, aches and pains (especially of the hip, knee and shoulder) and difficulty in movement. If you notice any of these symptoms tell your doctor.

  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 disopraxil may also cause loss of bone mass. The most pronounced bone loss was seen in clinical studies when patients were treated 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.

Tell your doctor if you know you suffer from osteoporosis. Patients with osteoporosis are at a higher risk for fractures.
- **Talk to your doctor if you have a history of 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 for you. If you have a history of liver disease or chronic hepatitis B infection your doctor may conduct blood tests to monitor your liver function.
- **Look out for infections.** If you have advanced HIV infection (AIDS) and have an infection, you may develop symptoms of infection and inflammation or worsening of the symptoms of an existing infection once treatment with tenofovir is started. These symptoms may indicate that your body's improved immune system is fighting infection. Look out for signs of inflammation or infection soon after you start taking Tenofovir 245 mg film-coated tablets. If you notice signs of inflammation or infection, **tell your doctor at once.**

  In addition to the opportunistic infections, autoimmune disorders (a condition that occurs when the immune system attacks healthy body tissue) may also occur after you start taking medicines for the treatment of your HIV infection. Autoimmune disorders may occur many months after the start of treatment. If you notice 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, please inform your doctor immediately to seek necessary treatment.
- **Talk to your doctor or pharmacist if you are over 65.** Tenofovir has not been studied in patients over 65 years of age. If you are older than this and are prescribed Tenofovir 245 mg film-coated tablets, your doctor will monitor you carefully.

Children and adolescents

Tenofovir 245 mg tablets are **suitable** for:
- **HIV-1 infected adolescents aged 12 to less than 18 years who weigh at least 35 kg and who have already been treated** with other HIV medicines which are no longer fully effective due to development of resistance, or have caused side effects.
- **HBV infected adolescents aged 12 to less than 18 years who weigh at least 35 kg.**

Tenofovir 245 mg tablets are **not** suitable for the following groups:
- **Not for HIV-1 infected children** under 12 years of age
- **Not for HBV infected children** under 12 years of age.

For dosage see section 3, *How to take Tenofovir 245 mg film-coated tablets.*

Other medicines and Tenofovir 245 mg film-coated tablets
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

- **Don't stop any anti-HIV medicines** prescribed by your doctor when you start Tenofovir 245 mg film-coated tablets if you have both HBV and HIV.
- **Do not take Tenofovir 245 mg film-coated tablets** if you are already taking other medicines containing tenofovir disoproxil or tenofovir alafenamide. Do not take Tenofovir 245 mg film-coated tablets together with medicines containing adefovir dipivoxil (a medicine used to treat chronic hepatitis B).
- **It is very important to tell your doctor if you are taking other medicines that may damage your kidneys.**

  These include:
  - aminoglycosides, pentamidine or vancomycin (for bacterial infection),
  - amphotericin B (for fungal infection),
  - foscarnet, ganciclovir, or cidofovir (for viral infection),
  - interleukin-2 (to treat cancer),
  - adefovir dipivoxil (for HBV),
  - tacrolimus (for suppression of the immune system),
  - non-steroidal anti-inflammatory drugs (NSAIDs, to relieve bone or muscle pains).
- **Other medicines containing didanosine (for HIV infection):** Taking Tenofovir 245 mg film-coated tablets 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 caused 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.
- **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.

Tenofovir 245 mg film-coated tablets with food and drink
Take Tenofovir 245 mg film-coated tablets with food (for example, a meal or a snack).

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 Tenofovir 245 mg film-coated tablets** during your pregnancy, your doctor may request regular blood tests and other diagnostic tests to monitor the development of your child.

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In children whose mothers took NRTIs during pregnancy, the benefit from the protection against HIV outweighed the risk of side effects.

- If you are a mother with HBV, and your baby has been given treatment to prevent hepatitis B transmission at birth, you may be able to breast-feed your infant, but first talk to your doctor to get more information.
- 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
Tenofovir 245 mg film-coated tablets can cause dizziness. If you feel dizzy while taking this medicine, **do not drive or ride a bicycle** and do not use any tools or machines.

Tenofovir 245 mg film-coated tablets contains lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Tenofovir 245 mg film-coated tablets contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Tenofovir 245 mg film-coated tablets

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is:
- **Adults:** 1 tablet each day with food (for example, a meal or a snack).
- **Adolescents aged 12 to less than 18 years who weigh at least 35 kg:** 1 tablet each day with food (for example, a meal or a snack).

If you have particular 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 an adult and have problems with your kidneys,** your doctor may advise you to take Tenofovir 245 mg film-coated tablets less frequently.
- If you have HBV your doctor may offer you an HIV test to see if you have both HBV and HIV.

Refer to the patient information leaflets of the other antiretrovirals for guidance on how to take those medicines.

If you take more Tenofovir 245 mg film-coated tablets than you should
If you accidentally take too many tablets, you may be at increased risk of experiencing possible side effects with this medicine (see section 4, *Possible side effects*). 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 forget to take Tenofovir 245 mg film-coated tablets
It is important not to miss a dose of Tenofovir 245 mg film-coated tablets. If you miss a dose, work out how long since you should have taken it.

- **If it is less than 12 hours** after it is usually taken, take it as soon as you can, and then take your next dose at its regular time.
- **If it is more than 12 hours** since you should have taken it, forget about the missed dose. Wait and take the next dose at the regular time. Do not take a double dose to make up for a forgotten tablet.

If you throw up less than 1 hour after taking Tenofovir 245 mg film-coated tablets, take another tablet. You do not need to take another tablet if you were sick more than 1 hour after taking Tenofovir 245 mg film-coated tablets.

If you stop taking Tenofovir 245 mg film-coated tablets
Don't stop taking Tenofovir 245 mg film-coated tablets without your doctor's advice. Stopping treatment with Tenofovir 245 mg film-coated tablets may reduce the effectiveness of the treatment recommended by your doctor.

If you have hepatitis B or HIV and hepatitis B together (co-infection), it is very important not to stop your Tenofovir 245 mg film-coated tablets treatment without talking to your doctor first. Some patients have had blood tests or symptoms indicating that their hepatitis has got worse after stopping Tenofovir 245 mg film-coated tablets. 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.

- Talk to your doctor before you stop taking Tenofovir 245 mg film-coated tablets for any reason, particularly if you are experiencing any side effects or you have another illness.
- Tell your doctor immediately about new or unusual symptoms after you stop treatment, particularly symptoms you associate with hepatitis B infection.
- Contact your doctor before you restart taking Tenofovir 245 mg film-coated tablets.

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

4. Possible side effects

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 life style, and in the case of blood lipids sometimes to the HIV medicines themselves. Your doctor will test for these changes.

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

Possible serious side effects: tell your doctor immediately

- **Lactic acidosis** (excess lactic acid in the blood) is a **rare** (may affect up to 1 in 1,000 people) but serious side effect that can be fatal. The following side effects may be signs of lactic acidosis:
  - deep, rapid breathing
  - drowsiness
  - feeling sick (nausea), being sick (vomiting) and stomach pain

→ If you think that you may have **lactic acidosis, contact your doctor immediately.**

Other possible serious side effects
The following side effects are **uncommon** (*may affect up to 1 in 100 people*):
- **pain in the tummy** (abdomen) caused by inflammation of the pancreas
- damage to kidney tubule cells

The following side effects are **rare** (*may affect up to 1 in 1,000 people*):
- inflammation of the kidney, **passing a lot of urine and feeling thirsty**
- **changes to** your **urine** and **back pain** caused by kidney problems, including kidney failure
- softening of the bones (with **bone pain** and sometimes resulting in fractures), which may occur due to damage to kidney tubule cells
- **fatty liver**

→ **If you think that you may have any of these serious side effects, talk to your doctor.**

Most frequent side effects
The following side effects are **very common** (*may affect more than 1 in 10 people*):
- diarrhoea, being sick (vomiting), feeling sick (nausea), dizziness, rash, feeling weak

Tests may also show:
- decreases in phosphate in the blood

Other possible side effects
The following side effects are **common** (*may affect up to 1 in 10 people*):
- headache, stomach pain, feeling tired, feeling bloated, flatulence

Tests may also show:
- liver problems

The following side effects are **uncommon** (*may affect up to 1 in 100 people*):
- breakdown of muscle, muscle pain or weakness

Tests may also show:
- decreases in potassium in the blood
- increased creatinine in your blood
- pancreas problems

The 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 may occur due to damage to kidney tubule cells.

The following side effects are **rare** (*may affect up to 1 in 1,000 people*):
- pain in the tummy (abdomen) caused by inflammation of the liver
- swelling of the face, lips, tongue or throat

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 at 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 Tenofovir 245 mg film-coated tablets

- 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 bottle and carton after {EXP}. The expiry date refers to the last day of that month.
- This medicine does not require any special storage conditions.
- Use within 30 days after first opening; store under 25 °C.
- 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 Tenofovir 245 mg film-coated tablets contains

– **The active substance is** tenofovir.
Each tablet contains 245 mg of tenofovir disoproxil (as succinate).

- **The other ingredients are:**
lactose, microcrystalline cellulose 112 (E460), pregelatinised starch, croscarmellose sodium and magnesium stearate (E470b) which make up the tablet core, and Indigo Carmine Aluminium Lake (E132), titanium dioxide (E171), Poly(Vinyl Alcohol) (E1203), Macrogol 3350 (E1521) and Talc (E553b) which make up the tablet coating. Refer to section 2 "Tenofovir 245 mg film-coated tablets contains lactose".

What Tenofovir 245 mg film-coated tablets look like and contents of the pack
Tenofovir 245 mg film-coated tablets are light blue, almond-shaped, with dimensions of approximately 17.0 mm x 10.5 mm.

Tenofovir 245 mg film-coated tablets are supplied in bottles containing 30 tablets. Each bottle contains a silica gel desiccant that must be kept in the bottle to help protect your tablets. The silica gel desiccant is contained in a separate canister and should not be swallowed.

The following pack sizes are available:
30 (1 x 30) film-coated tablets
90 (3 x 30) film-coated tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
STADA,
Linthwaite, Huddersfield, HD7 5QH, UK

Manufacturer
Remedica Ltd.,
Aharnon Street, Limassol Industrial Estate,
Limassol, Cyprus

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