



Package leaflet:
Information for the user

**Tenofovir disoproxil 204 mg
film-coated tablets**

tenofovir disoproxil

Read all of this leaflet carefully before your child starts 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 child's doctor or pharmacist.
- This medicine has been prescribed for your child only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as your child's.
- If your child gets any side effects, talk to your child's doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Tenofovir disoproxil is and what it is used for
2. What you need to know before your child takes Tenofovir disoproxil
3. How to take Tenofovir disoproxil
4. Possible side effects
5. How to store Tenofovir disoproxil
6. Contents of the pack and other information

1. What Tenofovir disoproxil is and what it is used for

Tenofovir disoproxil contains 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 an enzyme (in HIV *reverse transcriptase*, in hepatitis B *DNA polymerase*) that are essential for the viruses to reproduce themselves. In HIV Tenofovir disoproxil should always be used combined with other medicines to treat HIV infection.

Tenofovir disoproxil 204 mg tablets are a treatment for HIV (Human Immunodeficiency Virus) infection.

Tenofovir disoproxil 204 mg tablets are for use in children. They are only suitable for:

- **children aged 6 to less than 12 years**
- **who weigh from 28 kg to less than 35 kg**
- **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 disoproxil 204 mg tablets are also a treatment for chronic hepatitis B, an infection with HBV (hepatitis B virus).

Tenofovir disoproxil 204 mg tablets are for use in children. They are only suitable for:

- **children aged 6 to less than 12 years**
- **who weigh from 28 kg to less than 35 kg**

Your child does not have to have HIV to be treated with Tenofovir disoproxil 204 mg for HBV.

This medicine is not a cure for HIV infection. While taking Tenofovir disoproxil your child may still develop infections or other illnesses associated with HIV infection. Your child can also pass on HIV or HBV to others, so it is important to take precautions to avoid infecting other people.

2. What you need to know before your child takes Tenofovir disoproxil

Do not give Tenofovir disoproxil

- **If your child is allergic** to tenofovir, tenofovir disoproxil or any of the other ingredients of this medicine listed in section 6.
- If this applies to your child, **tell their doctor immediately and don't give Tenofovir disoproxil.**

Warnings and precautions

- For HIV, Tenofovir disoproxil 204 mg tablets are only suitable **for children 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.
- **Check your child's age and weight** to see if Tenofovir disoproxil 204 mg tablets are suitable, see *Children and adolescents*.

Talk to your child's doctor or pharmacist before giving Tenofovir disoproxil.

- **Take care not to infect other people.** Your child can still pass on HIV when taking this medicine, although the risk is lowered by effective antiretroviral therapy. Tenofovir disoproxil does not reduce the risk of passing on HBV to others through sexual contact or blood contamination. Discuss with your child's doctor the precautions needed to avoid infecting other people.
- Talk to your child's doctor or pharmacist if your child has had kidney disease or if tests have shown problems with their kidneys. Tenofovir disoproxil should not be given to children with existing kidney problems. Tenofovir disoproxil may affect your child's kidneys during treatment. Before starting treatment, your child's doctor may order blood tests to assess your child's kidney function. Your child's doctor may also order blood tests during treatment to monitor how your child's kidneys work.

Tenofovir disoproxil is not usually taken with other medicines that can damage your child's kidneys (see *Other medicines and Tenofovir disoproxil*). If this is unavoidable, your child's doctor will monitor your child's 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 child's 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 child's doctor if your child has 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 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 child's doctor if your child suffers from osteoporosis. Patients with osteoporosis are at a higher risk for fractures.

- **Talk to your child's doctor if your child has 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 your child has hepatitis B infection, your child's doctor will carefully consider the best treatment for them. If your child has a history of liver disease or chronic hepatitis B infection your child's doctor may conduct blood tests to monitor their liver function.
- **Look out for infections.** If your child has advanced HIV infection (AIDS) and has an infection, they may develop symptoms of infection and inflammation or worsening of the symptoms of an existing infection once treatment with tenofovir disoproxil is started. These symptoms may indicate that your child's body's improved immune system is fighting infection. Look out for signs of inflammation or infection soon after your child starts taking tenofovir disoproxil . If you notice signs of inflammation or infection, **tell your child's 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 your child starts taking medicines for the treatment of their HIV infection. Autoimmune disorders may occur many months after the start of treatment. If you notice that your child has 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 child's doctor immediately to seek necessary treatment.

Children and adolescents

Tenofovir disoproxil 204 mg tablets are **only suitable** for:

- **HIV-1 infected children aged 6 to less than 12 years who weigh from 28 kg to less than 35 kg 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 children aged 6 to less than 12 years who weigh from 28 kg to less than 35 kg**

Tenofovir disoproxil 204 mg tablets are **not** suitable for the following groups:

- **Not for** children who weigh under 28 kg or 35 kg and over. Contact your child's doctor if your child is outside the permitted weight.
- **Not for** children and adolescents under 6 years or 12 years and over.

For dosage see section 3, How to take Tenofovir disoproxil.

Other medicines and Tenofovir disoproxil

Tell your child's doctor or pharmacist if they are taking, have recently taken or might take any other medicines.

- Don't stop any anti-HIV medicines prescribed by your child's doctor when they start Tenofovir disoproxil if they have both HBV and HIV.
- **Do not give Tenofovir disoproxil** if your child is already taking other medicines containing tenofovir disoproxil or tenofovir alafenamide. Do not give Tenofovir disoproxil together with medicines containing adefovir dipivoxil (a medicine used to treat chronic hepatitis B).
- **It is very important to tell your child's doctor if your child is taking other medicines that may damage their 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 disoproxil with other antiviral medicines that contain didanosine can raise the levels of didanosine in the 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 child's doctor will carefully consider whether to treat your child with combinations of tenofovir and didanosine.
- **It is also important to tell your doctor** if your child is taking ledipasvir/sofosbuvir, sofosbuvir/velpatasvir or sofosbuvir/velpatasvir/voxilaprevir to treat hepatitis C infection.

Tenofovir disoproxil with food and drink

Give tenofovir disoproxil with food (for example, a meal or a snack).

Pregnancy and breast-feeding

If your child is pregnant or breast-feeding, or they think they may be pregnant, ask your child's doctor or pharmacist for advice before they take this medicine.

- **If your child has taken tenofovir disoproxil** during their pregnancy, your child's doctor may request regular blood tests and other diagnostic tests to monitor the development of the baby. In children whose mothers took medicines like tenofovir disoproxil (NRTIs) during pregnancy, the benefit from the protection against the virus outweighed the risk of side effects.
- If your child has HBV, and their baby has been given treatment to prevent hepatitis B transmission at birth, your child may be able to breast-feed their infant, but first talk to your child's doctor to get more information.
- If your child has HIV they must not breast-feed, to avoid passing the virus to the baby in breast milk.

Driving and using machines

Tenofovir disoproxil can cause dizziness.

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If your child feels dizzy while taking tenofovir disoproxil, they must **not drive or ride a bicycle** and must not use any tools or machines.

Tenofovir disoproxil contains lactose
Tell your child's doctor before giving Tenofovir disoproxil. If you have been told by your child's doctor that your child has an intolerance to some sugars, contact your child's doctor before they take this medicinal product.

Tenofovir disoproxil contains Sodium
This medicine contains less than 1 mmol sodium (23 mg) per dosage unit, that is to say essentially 'sodium-free'.

3. How to take Tenofovir disoproxil

Your child must always take this medicine exactly as their doctor or pharmacist has told you. Check with your child's doctor or pharmacist if you are not sure.

The recommended dose is:

- **Children aged 6 to less than 12 years who weigh from 28 kg to less than 35 kg:** 1 tablet each day with food (for example, a meal or a snack).

Your child's doctor will monitor their weight.

Your child must always take the dose recommended by their doctor. This is to make sure that their medicine is fully effective, and to reduce the risk of developing resistance to the treatment. Do not change the dose unless your child's doctor tells you to.

For HIV, your child's doctor will prescribe Tenofovir disoproxil with other antiretroviral medicines.

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

If your child takes more Tenofovir disoproxil than they should

If your child accidentally takes too many Tenofovir disoproxil tablets, they may be at increased risk of experiencing possible side effects with this medicine (see section 4, Possible side effects). Contact your child's doctor or nearest emergency department for advice. Keep the tablet bottle with you so that you can easily describe what your child has taken.

If your child forgets to take Tenofovir disoproxil

It is important not to miss a dose of Tenofovir disoproxil. If your child misses a dose, work out how long since they should have taken it.

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

If your child throws up less than 1 hour after taking Tenofovir disoproxil, give your child another tablet. Your child does not need to take another tablet if they were sick more than 1 hour after taking Tenofovir disoproxil.

If your child stops taking Tenofovir disoproxil

Your child must not stop taking Tenofovir disoproxil without their doctor's advice. Stopping treatment with Tenofovir disoproxil may reduce the effectiveness of the treatment recommended by your child's doctor.

If your child has hepatitis B or HIV and hepatitis B together (co-infection), it is very important not to stop their Tenofovir disoproxil treatment without talking to your child's doctor first. Some patients have had blood tests or symptoms indicating that their hepatitis has got worse after stopping Tenofovir disoproxil. Your child 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 child's hepatitis.

- Talk to your child's doctor before your child stops taking Tenofovir disoproxil for any reason, particularly if your child is experiencing any side effects or they have another illness.
- Tell your child's doctor immediately about new or unusual symptoms after your child stops treatment, particularly symptoms you associate with hepatitis B infection.
- Contact your child's doctor before your child restarts taking Tenofovir disoproxil tablets.

If you have any further questions on the use of this medicine, ask your child's 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 child's 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 child's doctor immediately

- **Lactic acidosis** (excess lactic acid in the blood) is a **rare** (can affect up to 1 in every 1,000 patients) 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 your child may have **lactic acidosis, contact your child's doctor immediately.**

Other possible serious side effects

The following side effects are **uncommon** (this can affect up to 1 in every 100 patients):

- **pain in the tummy** (abdomen) caused by inflammation of the pancreas
- damage to kidney tubule cells

The following side effects are **rare** (these can affect up to 1 in every 1,000 patients):

- inflammation of the kidney, **passing a lot of urine and feeling thirsty**
- **changes to your child's 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 your child may have any of these serious side effects, talk to your child's doctor.

Most frequent side effects

The following side effects are **very common** (these can affect at least 10 in every 100 patients):

- 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** (these can affect up to 10 in every 100 patients):

- flatulence

Tests may also show:

- liver problems

The following side effects are **uncommon** (these can affect up to 1 in every 100 patients):

- breakdown of muscle, muscle pain or weakness

Tests may also show:

- decreases in potassium in the blood
- increased creatinine in your child's 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** (these can affect up to 1 in every 1,000 patients):

- pain in the tummy (abdomen) caused by inflammation of the liver
- swelling of the face, lips, tongue or throat

Reporting of side effects

If your child gets any side effects, talk to your child's doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via 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 disoproxil

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

Store below 30°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 disoproxil contains

- The active substance is tenofovir disoproxil.

Each film-coated tablet contains 204 mg of tenofovir disoproxil (as fumarate).

- The other ingredients are
 - Tablet Core:* Croscarmellose sodium, lactose monohydrate, cellulose, microcrystalline, Starch, pregelatinized (Maize Starch) and magnesium stearate
 - Tablet coating:* Hypromellose 2910, lactose monohydrate, titanium dioxide (E 171), triacetin.

What Tenofovir disoproxil looks like and contents of the pack

Film-coated tablet.

White to off white, capsule shaped, biconvex film-coated tablets debossed with '250' on one side and 'T' on the other side.

Tenofovir disoproxil film-coated tablets are available in blister packs and HDPE bottle packs.

Packsizes:

Blister packs: 30 film-coated tablets.

HDPE packs: 30 and 90 film-coated tablets.

Not all pack sizes may be marketed.

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