



Tenofovir disoproxil maleate film coated tablet 300 mg

What is in this leaflet

Please read this leaflet carefully before you start taking Tenofovir Disoproxil Viatrix.

This leaflet answers some common questions about Tenofovir Disoproxil Viatrix.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Tenofovir Disoproxil Viatrix against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What Tenofovir Disoproxil Viatrix is used for

Tenofovir Disoproxil Viatrix is used to treat:

- Human Immunodeficiency Virus (HIV) infected adults and children 12 years of age and older
- Chronic Hepatitis B (CHB) in adults and children 12 years of age and older.

Tenofovir Disoproxil Viatrix contains the active ingredient tenofovir disoproxil maleate. It belongs to a group of medicines called HBV polymerase inhibitors and

nucleotide analog reverse transcriptase inhibitors (NRTI).

How Tenofovir Disoproxil Viatrix works in the treatment of CHB

Tenofovir Disoproxil Viatrix is used to treat CHB (an infection with hepatitis B virus [HBV]) in adults and paediatric patients 12 years and older and weighing at least 35 kg.

Tenofovir Disoproxil Viatrix works by interfering with the normal working enzymes (HBV DNA polymerase) that are essential for HBV to reproduce itself. Tenofovir Disoproxil Viatrix may help lower the amount of hepatitis B virus in your body by lowering the ability of the virus to multiply and infect new liver cells and can improve the inflammation and scar tissue caused by the hepatitis B virus in your liver. Lowering the amount of virus in your body may reduce the chance of developing cirrhosis, liver failure and liver cancer.

We do not know how long Tenofovir Disoproxil Viatrix may help treat your hepatitis.

Sometimes viruses change in your body and medicines no longer work. This is called drug resistance.

How Tenofovir Disoproxil Viatrix works in the treatment of HIV-infection

Tenofovir Disoproxil Viatrix is also used to treat HIV infection in adults and paediatric patients aged 12 years and older and weighing at least 35 kg. Tenofovir Disoproxil Viatrix is always used in combination with other anti-HIV medicines to treat people with HIV-1 infection.

HIV infection destroys CD4 (T) cells, which are important to the immune system. After a large

number of T cells are destroyed, acquired immune deficiency syndrome (AIDS) develops.

Tenofovir Disoproxil Viatrix helps to block HIV-1 reverse transcriptase, a chemical (enzyme) in your body that is needed for HIV-1 to multiply. Tenofovir Disoproxil Viatrix lowers the amount of HIV-1 in the blood (called viral load) and may help to increase the number of T cells (called CD4 cells). Lowering the amount of HIV-1 in the blood lowers the chance of death or infections that happen when your immune system is weak (opportunistic infections).

Use in Children

Tenofovir Disoproxil Viatrix is for adults and paediatric patients aged 12 years and older and weighing at least 35 kg.

Your doctor may have prescribed this medicine for another reason.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

This medicine is available only with a doctor's prescription.

Does Tenofovir Disoproxil Viatrix cure HIV or AIDS

Tenofovir Disoproxil Viatrix does not cure HIV infection or AIDS.

The long-term effects of Tenofovir Disoproxil Viatrix are not known at this time. People taking Tenofovir Disoproxil Viatrix may still get opportunistic infections or other conditions that happen with HIV-1 infection.

Opportunistic infections are infections that develop because the immune system is weak. Some of these conditions are:

- Pneumonia
- Herpes virus infection, and
- *Mycobacterium avium complex* (MAC) infection.

Does Tenofovir Disoproxil Viatris reduce the risk of passing HIV-1 or HBV to others

Tenofovir Disoproxil Viatris does not reduce the risk of passing HIV-1 or HBV to others through sexual contact or blood contamination.

Continue to practice safe sex and do not use or share dirty needles.

Before you take Tenofovir Disoproxil Viatris

When you must not take it

Do not take Tenofovir Disoproxil Viatris if you have an allergy to:

- any medicine containing tenofovir
- any of the ingredients listed at the end of this leaflet.
- Some of the symptoms of an allergic reaction may include: shortness of breath; wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not take Tenofovir Disoproxil Viatris if you are already taking any other medicines that contain the same active ingredients.

Do not take Tenofovir Disoproxil Viatris if you are already taking adefovir dipivoxil to treat hepatitis B virus (HBV) infection.

Do not take Tenofovir Disoproxil Viatris if you are already taking

tenofovir alafenamide to treat HIV or hepatitis B virus (HBV) infection.

Do not give this medicine to a child under the age of 12 years. Safety and effectiveness in children younger than 12 years have not been established.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding. The effects of Tenofovir Disoproxil Viatris on pregnant women or their unborn babies are not known.

Do not breast-feed if you are taking Tenofovir Disoproxil Viatris. The active substance in this medicine has been found in breast milk at low concentrations.

Do not breast-feed if you have HIV or HBV.

If you are a woman who has or will have a baby, talk with your doctor or pharmacist about the best way to feed your baby. If your baby does not already have HIV or HBV, there is a chance that the baby can get HIV or HBV through breast-feeding.

Tell your doctor if you have kidney problems.

Tell your doctor if you have bone problems.

Tell your doctor if you have liver problems, including HBV and hepatitis C virus (HCV).

Tell your doctor if you have HIV infection.

Tell your doctor or pharmacist about all your medical conditions.

Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell them before you start taking Tenofovir Disoproxil Viatris.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop.

You should also tell any health professional who is prescribing a new medication for you that you are taking Tenofovir Disoproxil Viatris.

Some medicines may interfere with Tenofovir Disoproxil Viatris. These include:

- sofosbuvir/velpatasvir/voxilaprevir, ledipasvir/sofosbuvir or sofosbuvir/velpatasvir to treat your HCV infection. These medicines may increase the amount of Tenofovir Disoproxil Viatris in your blood, which could result in additional or more intense side effects (see SIDE EFFECTS).
- didanosine; Tenofovir Disoproxil Viatris may increase the amount of didanosine in your blood. You may need to be followed more carefully if you are taking didanosine and Tenofovir Disoproxil Viatris together. Your doctor may need to reduce your dose of didanosine.
- atazanavir sulfate or lopinavir/ritonavir. These medicines may increase the amount of Tenofovir Disoproxil Viatris in your blood, which could result in more side effects (see SIDE EFFECTS). You may need to be followed more carefully if you are taking Tenofovir Disoproxil Viatris and atazanavir sulfate or lopinavir/ritonavir together. Tenofovir Disoproxil Viatris may decrease the amount of atazanavir sulfate in your blood. If you are taking

Tenofovir Disoproxil Viatrix and atazanavir sulfate together you should also be taking ritonavir.

These medicines may be affected by Tenofovir Disoproxil Viatrix or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take Tenofovir Disoproxil Viatrix

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the bottle, ask your doctor or pharmacist for help.

How much to take

The usual dose of Tenofovir Disoproxil Viatrix is one tablet once a day.

If you have kidney problems, your doctor may recommend that you take Tenofovir Disoproxil Viatrix less frequently.

How to take it

Swallow the tablet whole with a full glass of water.

If you are taking Tenofovir Disoproxil Viatrix to treat HIV or if you have HIV and HBV coinfection and are taking Tenofovir Disoproxil Viatrix, always take Tenofovir Disoproxil Viatrix in combination with other anti-HIV medicines.

Tenofovir Disoproxil Viatrix and other medicines like it, may be less likely to work in the future if you are not taking Tenofovir Disoproxil Viatrix with other anti-HIV medicines because you may develop resistance to those medicines. If

you have any questions about what medicines you should or should not be taking, please see your doctor or pharmacist.

If you have been given Tenofovir Disoproxil Viatrix to treat CHB, you are advised to get a HIV test before you start taking Tenofovir Disoproxil Viatrix and at any time after that when there is a chance you were exposed to HIV.

When your Tenofovir Disoproxil Viatrix supply starts to run low, get more from your doctor or pharmacist.

This is very important because the amount of virus in your blood may increase if the medicine is stopped for even a short time. The virus may develop resistance to Tenofovir Disoproxil Viatrix, and may become harder to treat. If you are taking Tenofovir Disoproxil Viatrix to treat CHB, stopping treatment may result in very severe hepatitis and serious liver problems (see SIDE EFFECTS).

Only take medicine that has been prescribed specifically for you.

Do not give Tenofovir Disoproxil Viatrix to others or take medicines prescribed for someone else.

When to take it

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

Tenofovir Disoproxil Viatrix is best taken with a meal or just afterwards, however taking it without food should not reduce the effectiveness of the medicine.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

If you forget to take it

It is important that you do not miss any doses.

If you miss a dose of Tenofovir Disoproxil Viatrix, take it as soon as you remember, and then go back to taking your medicine as you would normally.

If it is almost time for your next dose, do not take the missed dose. Wait and take the next dose at the regular time.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

While you are taking Tenofovir Disoproxil Viatrix

Things you must do

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Tenofovir Disoproxil Viatrix.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery.

If you become pregnant while taking this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are taking this medicine. It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Things you must not do

Do not take Tenofovir Disoproxil Viatris to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

If you stop taking it suddenly, your condition may worsen or you may have unwanted side effects.

Do not breast-feed. See “Before you start to take it”.

Things to be careful of

Be careful driving or operating machinery until you know how Tenofovir Disoproxil Viatris affects you.

This medicine may cause dizziness in some people. If you feel dizzy, do not drive, operate machinery or do anything else that could be dangerous.

Be careful when drinking alcohol while you are taking this medicine.

If you drink alcohol, dizziness may be worse.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much Tenofovir Disoproxil Viatris. Do this even if there are no signs of discomfort

or poisoning. You may need urgent medical attention.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Tenofovir Disoproxil Viatris

This medicine helps most people with HIV or HBV infection but it may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

In clinical studies in patients with HIV the most common side effects of Tenofovir Disoproxil were:

- diarrhoea
- nausea
- vomiting
- dizziness

Less common side effects of Tenofovir Disoproxil were:

- flatulence (intestinal gas)

In clinical studies in patients with CHB the only side effect of Tenofovir Disoproxil was:

- nausea

Marketing experience has shown other side effects reported since Tenofovir Disoproxil has been marketed and include:

- low blood phosphate
- shortness of breath
- increased liver enzymes
- increased amylase
- inflammation of the liver
- stomach pain
- inflammation of the pancreas
- rash
- weakness

Tenofovir Disoproxil Viatris may cause the following other side effects:

Kidney Problems

Some patients treated with Tenofovir Disoproxil Viatris have had kidney problems. If you have had kidney problems in the past or need to take another drug that can cause kidney problems, your doctor may need to perform additional blood tests.

Kidney problems may be associated with muscle problems and softening of the bones.

Changes in Bone Mineral Density

Laboratory tests show changes in the bones of patients treated with Tenofovir Disoproxil. It is not known whether long-term use of Tenofovir Disoproxil will cause damage to your bones. If you have had bone problems in the past, your doctor may need to perform additional tests or may suggest additional medication.

Lactic Acidosis

Some patients taking antiviral drugs like Tenofovir Disoproxil Viatris have developed a condition called lactic acidosis (a build-up in the blood of lactic acid, the same substance that causes your muscles to burn during heavy exercise). Symptoms of lactic acidosis include nausea, vomiting, unusual or unexpected stomach discomfort, and weakness.

If you notice these symptoms or if your medical condition changes suddenly, call your doctor right away.

Hepatic Flares

It is extremely important that you do not stop taking Tenofovir Disoproxil Viatris without your doctor's advice. If you have Hepatitis B infection or HIV and HBV infection together, you may have a “flare-up” of Hepatitis B if you stop taking Tenofovir Disoproxil Viatris, where the disease suddenly returns in a worse way than before. This flare-up may lead to liver failure and possibly liver transplantation or death.

After stopping Tenofovir Disoproxil Viatris, tell your doctor immediately about any new, unusual, or worsening symptoms that you notice after stopping treatment. After you stop taking Tenofovir Disoproxil Viatris, your doctor will still need to check your health and take blood tests to check your liver for several months.

There have been other side effects in patients taking Tenofovir Disoproxil.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After taking Tenofovir Disoproxil Viatris

Storage

Keep your tablets in the bottle until it is time to take it.

If you take the tablets out of the bottle they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 25°C.

Do not store Tenofovir Disoproxil Viatris or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Light blue coloured, round, biconvex, film coated tablets debossed with 'TM300' on one side of the tablet and 'M' on other side.

Ingredients

Active ingredient:

Tenofovir Disoproxil Viatris contains 300 mg of tenofovir disoproxil maleate as the active ingredient.

Inactive ingredients:

Tenofovir Disoproxil Viatris also contains:

- Microcrystalline cellulose (PH 112)
- Lactose monohydrate
- Low-substituted hydroxypropyl cellulose
- Colloidal anhydrous silica
- Magnesium stearate
- HMPC 2910/Hypromellose
- Titanium dioxide
- Triacetin
- FD&C Blue #2
- Indigo carmine aluminium lake

Contains sugars as lactose.

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine

Tenofovir Disoproxil Viatris is supplied in New Zealand by:

Viatris Ltd
PO Box 11-183
Eilerslie
AUCKLAND
www.viatris.co.nz
Telephone 0800 168 169

Date of Preparation

8 June 2022.

(Based on datasheet dated 8 June 2022)