

# TENOFOVIR DISOPROXIL VIATRIS

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## **Consumer Medicine Information (CMI) summary**

The [full CMI](#) on the next page has more details. If you are worried about taking this medicine, speak to your doctor or pharmacist.

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### **1. Why am I taking TENOFOVIR DISOPROXIL VIATRIS?**

TENOFOVIR DISOPROXIL VIATRIS contains the active ingredient tenofovir disoproxil maleate. TENOFOVIR DISOPROXIL VIATRIS is an antiviral used to treat Chronic Hepatitis B (CHB) and Human Immunodeficiency Virus (HIV) infection.

For more information, see Section [1. Why am I taking TENOFOVIR DISOPROXIL VIATRIS?](#) in the full CMI.

### **2. What should I know before I take TENOFOVIR DISOPROXIL VIATRIS?**

Do not take if you have ever had an allergic reaction to TENOFOVIR DISOPROXIL VIATRIS or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I take TENOFOVIR DISOPROXIL VIATRIS?](#) in the full CMI.

### **3. What if I am taking other medicines?**

Some medicines may interfere with TENOFOVIR DISOPROXIL VIATRIS and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### **4. How do I take TENOFOVIR DISOPROXIL VIATRIS?**

- The usual dose of TENOFOVIR DISOPROXIL VIATRIS is one tablet once a day.
- Take TENOFOVIR DISOPROXIL VIATRIS exactly as your doctor prescribed it.

More instructions can be found in Section [4. How do I take TENOFOVIR DISOPROXIL VIATRIS?](#) in the full CMI.

## 5. What should I know while taking TENOFOVIR DISOPROXIL VIATRIS?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are taking TENOFOVIR DISOPROXIL VIATRIS.</li><li>• Stay under a doctor's care when taking TENOFOVIR DISOPROXIL VIATRIS.</li><li>• When your TENOFOVIR DISOPROXIL VIATRIS supply starts to run low, get more from your doctor or pharmacist.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not take TENOFOVIR DISOPROXIL VIATRIS for a condition for which it was not prescribed.</li><li>• Do not share TENOFOVIR DISOPROXIL VIATRIS with other people.</li><li>• Do not take if seal over bottle opening is broken or missing.</li></ul>

	<ul style="list-style-type: none"> <li>• Do not change your treatment or stop treatment without first talking with your doctor.</li> </ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"> <li>• Be careful before you drive or use any machines or tools until you know how TENOFOVIR DISOPROXIL VIATRIS affects you.</li> </ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"> <li>• Store TENOFOVIR DISOPROXIL VIATRIS at room temperature below 25°C.</li> <li>• Keep your TENOFOVIR DISOPROXIL VIATRIS tablets in the bottle with the cap tightly closed until you take them.</li> </ul>

For more information, see Section [5. What should I know while taking TENOFOVIR DISOPROXIL VIATRIS?](#) in the full CMI.

## 6. Are there any side effects?

Some common side effects are diarrhoea, nausea, vomiting, dizziness, flatulence (intestinal gas). TENOFOVIR DISOPROXIL VIATRIS may cause kidney problems, changes in bone mineral density, lactic

acidosis and hepatic flares. All medicines can have side effects. If they do occur, they are usually minor and temporary. Do not be alarmed by this list. You may not experience any of them. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# TENOFOVIR DISOPROXIL VIATRIS

**Active ingredient(s):** *tenofovir disoproxil maleate*

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## Consumer Medicine Information (CMI)

This leaflet provides important information about taking TENOFOVIR DISOPROXIL VIATRIS. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking TENOFOVIR DISOPROXIL VIATRIS.**

**Where to find information in this leaflet:**

- [1. Why am I taking TENOFOVIR DISOPROXIL VIATRIS?](#)
- [2. What should I know before I take TENOFOVIR DISOPROXIL VIATRIS?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I take TENOFOVIR DISOPROXIL VIATRIS?](#)
- [5. What should I know while taking TENOFOVIR DISOPROXIL VIATRIS?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I taking TENOFOVIR DISOPROXIL VIATRIS?

**TENOFOVIR DISOPROXIL VIATRIS contains the active ingredient tenofovir disoproxil maleate.**  
TENOFOVIR DISOPROXIL VIATRIS is a type of

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medicine called HBV polymerase inhibitor and a nucleotide analogue reverse transcriptase inhibitor (NRTI).

**TENOFOVIR DISOPROXIL VIATRIS is antiviral medication used to treat two different viruses;**

- Chronic Hepatitis B (CHB) and
- Human Immunodeficiency Virus (HIV) infection.

**How TENOFOVIR DISOPROXIL VIATRIS works in the Treatment of CHB:**

**TENOFOVIR DISOPROXIL VIATRIS is used to treat CHB (an infection with hepatitis B virus [HBV]) in adults and paediatric patients aged 12 years and older and weighing at least 35 kg.**

TENOFOVIR DISOPROXIL VIATRIS works by interfering with the normal working of enzymes (HBV DNA polymerase) that are essential for HBV to reproduce itself. TENOFOVIR DISOPROXIL VIATRIS 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 VIATRIS may help treat your hepatitis.

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

## **How TENOFOVIR DISOPROXIL VIATRIS works in the Treatment of HIV Infection:**

**TENOFOVIR DISOPROXIL VIATRIS 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 VIATRIS 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 VIATRIS helps to block HIV-1 reverse transcriptase, a chemical (enzyme) in your body that is needed for HIV-1 to multiply.

TENOFOVIR DISOPROXIL VIATRIS 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).

You do not have to have HIV infection to be treated with TENOFOVIR DISOPROXIL VIATRIS for HBV and vice versa.



## **Does TENOFOVIR DISOPROXIL VIATRIS cure HIV or AIDS?**

**TENOFOVIR DISOPROXIL VIATRIS does not cure HIV infection or AIDS.**

The long-term effects of TENOFOVIR DISOPROXIL VIATRIS are not known at this time. People taking TENOFOVIR DISOPROXIL VIATRIS 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 infections, and
- Mycobacterium avium complex
- (MAC) infections.

## **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.**

## **2. What should I know before I take TENOFOVIR DISOPROXIL VIATRIS?**

### **Warnings**

**Together with your doctor, you need to decide whether TENOFOVIR DISOPROXIL VIATRIS is right for you.**

**Do not take TENOFOVIR DISOPROXIL VIATRIS if:**

- you are allergic to:
  - tenofovir disoproxil maleate
  - tenofovir disoproxil fumarate
  - any of the ingredients listed at the end of this leaflet

Always check the ingredients to make sure you can take this medicine.

- you are already taking any other medicines containing tenofovir disoproxil maleate or tenofovir disoproxil fumarate
- you are already taking adefovir dipivoxil to treat hepatitis B virus (HBV) infection
- you are already taking tenofovir alafenamide to treat HIV or hepatitis B virus (HBV) infection.

**Check with your doctor if you:**

- have any of the following medical conditions:
  - kidney problems

- bone problems
- liver problems, including HBV and hepatitis C virus (HCV)
- HIV infection
- take any medicines for any other condition.

Tell your doctor or pharmacist about all your medical conditions.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

## **Pregnancy and breastfeeding**

**Tell your doctor if you are pregnant or planning to become pregnant.**

The effects of TENOFOVIR DISOPROXIL VIATRIS on pregnant women or their unborn babies are not known.

**Tell your doctor if you are breastfeeding.**

**Do not breastfeed if you are taking TENOFOVIR DISOPROXIL VIATRIS or if you have HIV or HBV.**

The active substance in this medicine (tenofovir disoproxil maleate) has been found in breast milk at low concentrations.

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 breastfeeding.

## Use in children

TENOFOVIR DISOPROXIL VIATRIS is for adults and paediatric patients aged 12 years and older and weighing at least 35 kg.

### 3. What if I am taking other medicines?

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

**Some medicines may interfere with TENOFOVIR DISOPROXIL VIATRIS and affect how it works. These include:**

- didanosine
- atazanavir sulfate
- lopinavir/ritonavir
- sofosbuvir/velpatasvir/voxilaprevir
- ledipasvir/sofosbuvir
- sofosbuvir/velpatasvir

These medicines may increase the amount of TENOFOVIR DISOPROXIL VIATRIS in your blood, which could result in more 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 VIATRIS and atazanavir sulfate together you should also be taking ritonavir.

**It is a good idea to keep a complete list of all the medicines that you take.**

Make a new list when medicines are added or stopped. Give copies of this list to your doctor or pharmacist every time you visit your doctor or fill a prescription.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect TENOFOVIR DISOPROXIL VIATRIS.**

## **4. How do I take TENOFOVIR DISOPROXIL VIATRIS?**

### **How much to take**

- Take TENOFOVIR DISOPROXIL VIATRIS exactly as your doctor prescribed it.
- Follow the directions from your doctor or pharmacist, exactly as written on the label.
- Set up a dosing schedule and follow it carefully.
- The usual dose of TENOFOVIR DISOPROXIL VIATRIS is one tablet once a day.
- If you have kidney problems, your doctor may recommend that you take TENOFOVIR DISOPROXIL VIATRIS less frequently.

## When to take TENOFOVIR DISOPROXIL VIATRIS

- TENOFOVIR DISOPROXIL VIATRIS is best taken with a meal or just afterwards, however taking it without food should not reduce the effectiveness of the medicine.

## How to take TENOFOVIR DISOPROXIL VIATRIS

- **If you are taking TENOFOVIR DISOPROXIL VIATRIS to treat HIV or if you have HIV and HBV coinfection and are taking TENOFOVIR DISOPROXIL VIATRIS, always take TENOFOVIR DISOPROXIL VIATRIS in combination with other anti-HIV medicines.**

TENOFOVIR DISOPROXIL VIATRIS and other medicines like TENOFOVIR DISOPROXIL VIATRIS, may be less likely to work in the future if you are not taking TENOFOVIR DISOPROXIL VIATRIS 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 VIATRIS to treat CHB, you are advised to get a HIV test before you start taking TENOFOVIR DISOPROXIL VIATRIS and at any time after that when there is a chance you were exposed to HIV.
- **Only take medicine that has been prescribed specifically for you.**

## **If you forget to take TENOFOVIR DISOPROXIL VIATRIS**

**It is important that you do not miss any doses.**

**If you miss a dose of TENOFOVIR DISOPROXIL VIATRIS, take it as soon as possible and then take your next scheduled dose at its regular time.**

**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 double the next dose.**

## **If you take too much TENOFOVIR DISOPROXIL VIATRIS**

**If you think that you or anyone else has taken too much TENOFOVIR DISOPROXIL VIATRIS, urgent medical attention may be needed.**

**You should immediately:**

- **phone the Poisons Information Centre (by calling 13 11 26) for advice, or**
- **contact your doctor, or**
- **go to the Emergency Department at your nearest hospital.**

**You should do this even if there are no signs of discomfort or poisoning.**

## **5. What should I know while taking TENOFOVIR DISOPROXIL VIATRIS?**

### **Things you should do**

- Stay under a doctor's care when taking TENOFOVIR DISOPROXIL VIATRIS.
- **When your TENOFOVIR DISOPROXIL VIATRIS 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 VIATRIS, and may become harder to treat. If you are taking TENOFOVIR DISOPROXIL VIATRIS to treat CHB, stopping treatment may result in very severe hepatitis and serious liver problems.

Remind any doctor, dentist or pharmacist you visit that you are taking TENOFOVIR DISOPROXIL VIATRIS.

### **Things you should not do**

- Do not take TENOFOVIR DISOPROXIL VIATRIS for a condition for which it was not prescribed.
- Do not share TENOFOVIR DISOPROXIL VIATRIS with other people.
- Do not take if seal over bottle opening is broken or missing.



- Do not change your treatment or stop treatment without first talking with your doctor.
- Do not give TENOFOVIR DISOPROXIL VIATRIS to others or take medicine prescribed for someone else.

## **Driving or using machines**

**Be careful before you drive or use any machines or tools until you know how TENOFOVIR DISOPROXIL VIATRIS affects you.**

Some patients taking TENOFOVIR DISOPROXIL VIATRIS have experienced dizziness. Make sure you know how you react to TENOFOVIR DISOPROXIL VIATRIS before you drive a car, operate machinery or do anything else that could be dangerous if you are dizzy.

## **Looking after your medicine**

- Store TENOFOVIR DISOPROXIL VIATRIS at room temperature below 25°C.  
It should remain stable until the expiration date printed on the label.
- Keep your TENOFOVIR DISOPROXIL VIATRIS tablets in the bottle with the cap tightly closed until you take them.

If you take TENOFOVIR DISOPROXIL VIATRIS tablets out of their bottle they may not keep well.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Heat and dampness can destroy some medicines.

**Keep it where young children cannot reach it.**

## **Getting rid of any unwanted medicine**

If you no longer need to take this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not take this medicine after the expiry date.

If you throw any medicines away make sure that children will not find them.

## **6. Are there any side effects?**

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

## Common side effects

Common side effects	What to do
<p><b>Clinical studies in patients with HIV:</b></p> <ul style="list-style-type: none"> <li>• diarrhoea</li> <li>• nausea</li> <li>• vomiting</li> <li>• dizziness</li> <li>• flatulence (intestinal gas)</li> </ul> <p><b>Clinical studies in patients with CHB:</b></p> <ul style="list-style-type: none"> <li>• nausea</li> </ul> <p><b>Marketing experience:</b></p> <ul style="list-style-type: none"> <li>• low blood phosphate</li> <li>• shortness of breath</li> <li>• increased liver enzymes</li> <li>• increased amylase</li> <li>• inflammation of the liver</li> <li>• stomach pain</li> <li>• inflammation of the pancreas</li> <li>• rash and weakness</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you or go straight to the Emergency Department.</b></p>

**TENOFOVIR DISOPROXIL VIATRIS may cause the following other side effects:**

**Kidney Problems:**

Some patients treated with tenofovir disoproxil 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 VIATRIS 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.**

However, these side effects may have been due to other medicines that patients were taking or to the illness itself.

**Some of these side effects can be serious.**

**This list of side effects is not complete. If you have questions about side effects, ask your doctor or pharmacist.**

**You should report any new or continuing symptoms to your doctor or pharmacist right away.**

Your doctor or pharmacist may be able to help you manage these side effects

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

## **Reporting side effects**

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## **7. Product details**

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

### **What TENOFOVIR DISOPROXIL VIATRIS contains**

<b>Active ingredient (main ingredient)</b>	tenofovir disoproxil maleate 300 mg
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<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"> <li>• microcrystalline cellulose</li> <li>• lactose monohydrate</li> <li>• hypromellose</li> <li>• colloidal anhydrous silica</li> <li>• magnesium stearate</li> <li>• OPADRY II complete film coating system 32K505018 BLUE (ID: 109808)</li> </ul>
<b>Potential allergens</b>	<ul style="list-style-type: none"> <li>• Sugars as lactose</li> </ul>

**Do not take this medicine if you are allergic to any of these ingredients.**

## **What TENOFOVIR DISOPROXIL VIATRIS looks like**

TENOFOVIR DISOPROXIL VIATRIS is 300 mg film coated tablets are light blue coloured, 12 mm, round, biconvex, film coated tablets debossed with 'TM300' on one side of the tablet and 'M' on other side (AUST R 261093).

## **Who distributes TENOFOVIR DISOPROXIL VIATRIS**

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road  
Millers Point NSW 2000

[www.viatris.com.au](http://www.viatris.com.au)

Phone: 1800 274 276

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