

# Tenofovir Sandoz®

## Consumer Medicine Information (CMI) summary

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

### 1. Why am I using Tenofovir Sandoz?

Tenofovir Sandoz contains the active ingredient tenofovir. Tenofovir Sandoz is used to treat two different viruses; Chronic Hepatitis B (CHB) and Human Immunodeficiency Virus (HIV) infection.

For more information, see Section [1. Why am I using Tenofovir Sandoz?](#) in the full CMI.

### 2. What should I know before I use Tenofovir Sandoz?

Do not use if you have ever had an allergic reaction to tenofovir 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 use Tenofovir Sandoz?](#) in the full CMI.

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

Some medicines may interfere with Tenofovir Sandoz 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 use Tenofovir Sandoz?

The usual dose of Tenofovir Sandoz is one tablet once a day. If you have kidney problems, your doctor may recommend that you take Tenofovir Sandoz less frequently.

More instructions can be found in Section [4. How do I use Tenofovir Sandoz?](#) in the full CMI.

### 5. What should I know while using Tenofovir Sandoz?

<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 Sandoz.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>Do not stop taking Tenofovir Sandoz or change the dose without first checking with your doctor.</li><li>Do not give Tenofovir Sandoz to anyone else even if they have the same condition as you.</li><li>Do not breastfeed.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>Be careful driving or operating machinery until you know how Tenofovir Sandoz affects you. This medicine may cause dizziness.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>Be careful when drinking alcohol while you are taking this medicine.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>Keep Tenofovir Sandoz in a cool dry place where the temperature stays below 25°C.</li></ul>

For more information, see Section [5. What should I know while using Tenofovir Sandoz?](#) in the full CMI.

### 6. Are there any side effects?

**Common side effects:** nausea, vomiting, diarrhoea, dizziness, flatulence (intestinal gas).

**Serious side effects:** low blood phosphate, shortness of breath, increased liver enzymes, inflammation of the liver and pancreas, rash, kidney problems, bone problems.

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 Sandoz®

Active ingredient(s): *tenofovir disoproxil fumarate*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using Tenofovir Sandoz. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Tenofovir Sandoz.**

Where to find information in this leaflet:

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

## 1. Why am I using Tenofovir Sandoz?

**Tenofovir Sandoz contains the active ingredient tenofovir disoproxil fumarate.** Tenofovir belongs to a group of medicines called HBV polymerase inhibitor and a nucleotide analog reverse transcriptase inhibitor (NRTI).

**Tenofovir Sandoz is used to treat two different viruses; Chronic Hepatitis B (CHB) and Human Immunodeficiency Virus (HIV) infection.**

### Treatment of CHB

Tenofovir Sandoz works by interfering with the normal working of enzymes (HBV DNA polymerase) that are essential for HBV to reproduce itself.

Tenofovir Sandoz 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 Sandoz may help treat your hepatitis. Sometimes viruses change in your body and medicines no longer work. This is called drug resistance.

### Treatment of HIV

Tenofovir Sandoz 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 Sandoz helps to block HIV-1 reverse transcriptase, a chemical (enzyme) in your body that is needed for HIV-1 to multiply. Tenofovir Sandoz 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 Sandoz for HBV and vice versa.

## 2. What should I know before I use Tenofovir Sandoz?

### Warnings

**Do not use Tenofovir Sandoz if:**

- you are allergic to tenofovir, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine. Some 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
- you are already taking any other medicines that contain the same active ingredients
- you are already taking adefovir dipivoxil or tenofovir alafenamide to treat HIV or hepatitis B virus (HBV) infection.

**Check with your doctor if you:**

- have any other medical conditions
  - kidney problems
  - liver problems, including HBV or Hepatitis C virus (HCV)
  - bone problems
  - HIV infection
- take any medicines for any other condition

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 intend to become pregnant.**

The effects of Tenofovir Sandoz on pregnant women on their unborn babies are not known.

**Do not take this medicine if you are breastfeeding or intend to breastfeed.**

Tenofovir disoproxil fumarate 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.

## Use in children

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

The safety and efficacy of tenofovir disoproxil fumarate has not been established in children less than 12 years of age.

## Does Tenofovir Sandoz cure HIV or AIDS

Tenofovir Sandoz does not cure HIV infection or AIDS. The long-term effects of Tenofovir Sandoz are not known at this time. People taking Tenofovir Sandoz 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) infection.

## Does Tenofovir Sandoz reduce the risk of passing HIV-1 or HBV to others?

**Tenofovir Sandoz 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.**

## 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 Sandoz and affect how it works. Tell your doctor or pharmacist if you take the following:**

- VOSEVI (sofosbuvir/velpatasvir/voxilaprevir), HARVONI (ledipasvir/sofosbuvir) or EPCLUSA (sofosbuvir/ velpatasvir) to treat your HCV infection. These medicines may increase the amount of TENOFOVIR SANDOZ in your blood, which could result in additional or more intense side effects.
- VIDEX, VIDEX EC (didanosine); TENOFOVIR SANDOZ may increase the amount of VIDEX in your blood. You may need to be followed more carefully if you are taking VIDEX and TENOFOVIR SANDOZ together. If you are taking VIDEX and TENOFOVIR SANDOZ together, your doctor may need to reduce your dose of VIDEX
- REYATAZ (atazanavir sulfate) or KALETRA (lopinavir/ritonavir); These medicines may increase the amount of TENOFOVIR SANDOZ in your blood,

which could result in more side effects. You may need to be followed more carefully if you are taking TENOFOVIR SANDOZ and REYATAZ or KALETRA together. TENOFOVIR SANDOZ may decrease the amount of REYATAZ in your blood. If you are taking TENOFOVIR SANDOZ and REYATAZ together you should also be taking NORVIR (ritonavir).

**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 Sandoz.**

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 in a prescription.

## 4. How do I use Tenofovir Sandoz?

**Stay under a doctor's care when taking Tenofovir Sandoz.**

**Do not change your treatment or stop treatment without first talking with your doctor.**

**Take Tenofovir Sandoz exactly as your doctor prescribed it.**

### How much to take

- The usual dose of Tenofovir Sandoz is one tablet once a day.
- If you have kidney problems, your doctor may recommend that you take Tenofovir Sandoz less frequently.

### How to take Tenofovir Sandoz

- **Tenofovir Sandoz is best taken with a meal or just afterwards, however taking it without food should not reduce the effectiveness of the medicine.**
- **If you are taking Tenofovir Sandoz to treat HIV or if you have HIV and HBV coinfection and are taking Tenofovir Sandoz, always take Tenofovir Sandoz in combination with other anti-HIV medicines.** Tenofovir Sandoz and other antivirals may be less likely to work in the future if you are not taking Tenofovir Sandoz with other anti-HIV medicines because you may develop resistance to those medicines.
- If you have been given Tenofovir Sandoz to treat CHB, you are advised to get a HIV test before you start taking Tenofovir Sandoz and at any time after that when there is a chance you were exposed to HIV.
- **When your Tenofovir Sandoz 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 Sandoz, and may become harder to treat. If you are taking Tenofovir Sandoz to treat CHB, stopping treatment may result in very severe hepatitis and serious liver problems.

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

### If you forget to use Tenofovir Sandoz

It is important that you do not miss any doses. Take your dose as soon as you remember, and continue to take it as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

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

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

### If you use too much Tenofovir Sandoz

If you think that you have used too much Tenofovir Sandoz, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), 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 using Tenofovir Sandoz?

### Things you should do

- If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Tenofovir Sandoz.

Remind any doctor, dentist or pharmacist you visit that you are using Tenofovir Sandoz.

### Things you should not do

- Do not stop taking Tenofovir Sandoz or change the dose without first checking with your doctor.
- Do not give Tenofovir Sandoz to anyone else even if they have the same condition as you.
- Do not breastfeed whilst taking the medicine.

### Driving or using machines

Be careful before you drive or use any machines or tools until you know how Tenofovir Sandoz affects you.

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

### Drinking alcohol

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

### Looking after your medicine

- Keep your Tenofovir Sandoz tablets in the bottle with the cap tightly closed until you take them. If you take the tablets out of their pack they may not keep well.

Store it in a cool dry place away from moisture, heat or sunlight below 25°C; for example, do not store it:

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

Keep it where young children cannot reach it.

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

### Getting rid of any unwanted medicine

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

Do not use this medicine after the expiry date.

## 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.

### Less serious side effects

Less serious side effects	What to do
<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>Speak to your doctor if you have any of these less serious side effects and they worry you.</p> <p>They are generally mild and do not cause patients to stop taking Tenofovir Sandoz.</p>

### Serious side effects

Serious side effects	What to do
<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</li></ul>	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you</p>

<ul style="list-style-type: none"> <li>weakness</li> </ul> <p><b>Kidneys Related</b></p> <ul style="list-style-type: none"> <li>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.</li> <li>Kidney problems may be associated with muscle problems and softening of the bones.</li> </ul> <p><b>Changes in Bone Mineral Density Related</b></p> <ul style="list-style-type: none"> <li>Laboratory tests show changes in the bones of patients treated with tenofovir.</li> <li>It is not known whether long-term use 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.</li> </ul> <p><b>Lactic Acidosis Related</b></p> <ul style="list-style-type: none"> <li>Some patients taking antiviral drugs like tenofovir 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).</li> <li>Symptoms of lactic acidosis include nausea, vomiting, unusual or unexpected stomach discomfort, and weakness.</li> </ul> <p><b>Changes in Body Fat Related</b></p> <ul style="list-style-type: none"> <li>Increased amounts of fat in the upper back and neck have been seen in patients taking antivirals.</li> <li>Symptoms include “buffalo hump”, breast, and around the main part of your body (trunk).</li> <li>Loss of fat from the legs, arms and face may also happen.</li> </ul> <p>The cause and long-term health effects of these conditions are not known at this time.</p> <p><b>Hepatic Flares Related</b></p> <ul style="list-style-type: none"> <li>It is extremely important that you do not stop taking tenofovir without your doctor’s advice.</li> <li>If you have Hepatitis B infection or HIV and HBV infection together, you may have a “flare</li> </ul>	<p><b>notice any of these serious side effects.</b></p>
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<p>up” of Hepatitis B if you stop taking tenofovir, 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.</p> <ul style="list-style-type: none"> <li>After stopping Tenofovir Sandoz, tell your doctor immediately about any new, unusual, or worsening symptoms that you notice after stopping treatment. Your doctor will still need to check your health and take blood tests to check your liver for several months.</li> </ul>	
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**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 Sandoz contains

<b>Active ingredient (main ingredient)</b>	tenofovir disoproxil fumarate
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"> <li>lactose monohydrate</li> <li>croscarmellose sodium</li> <li>microcrystalline cellulose</li> <li>pregelatinised maize starch</li> <li>magnesium stearate</li> <li>Film-coating: Opadry II White 32K180001 (ARTG 111615).</li> </ul>
<b>Potential allergens</b>	sugars as lactose

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

### What Tenofovir Sandoz looks like

Tenofovir Sandoz 300 mg – white coloured, almond shaped, film coated tablets debossed with ‘H’ on one side and ‘123’ on the other side – bottle pack of 30 tablets (Aust R 295606).

## **Who distributes Tenofovir Sandoz**

Sandoz Pty Ltd  
100 Pacific Highway  
North Sydney, NSW 2060  
Australia  
Tel 1800 726 369

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