

Tenofovir GH

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 GH?

Tenofovir GH contains the active ingredient tenofovir disoproxil phosphate. Tenofovir GH is used to an antiviral medication used to treat Chronic Hepatitis B (HBV) virus and Human Immunodeficiency Virus (HIV-1) infection in adults and children aged over 12 years and weighing at least 35 kg.

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

2. What should I know before I use Tenofovir GH?

Do not use if you have ever had an allergic reaction to tenofovir disoproxil phosphate or any of the ingredients listed at the end of the CMI.

Talk to your doctor or pharmacist 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 GH?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Tenofovir GH 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 GH?

- The usual dose of Tenofovir GH is one tablet once a day.
- Take Tenofovir GH exactly as prescribed by your doctor,

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

5. What should I know while using Tenofovir GH?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Tenofovir GH.• Contact your doctor immediately if you become pregnant.
Things you should not do	<ul style="list-style-type: none">• Do not breastfeed if you are taking Tenofovir GH.• Do not give this medicine to anyone else, even if they have the same condition as you.• Do not take your medicine to treat any other complaint unless your doctor tells you to.
Driving or using machines	<ul style="list-style-type: none">• Do not drive or use any machines or tools until you know how Tenofovir GH affects you.• Some patients taking this medicine have experienced dizziness.
Drinking alcohol	<ul style="list-style-type: none">• Tell your doctor if you drink alcohol if you are prescribed Tenofovir GH.
Looking after your medicine	<ul style="list-style-type: none">• Keep your medicine in a cool dry place where the temperature will stay below 25°C.• Keep your medicine in its pack until it is time to take it. If you take your medicine out of its pack it may not keep well.

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

6. Are there any side effects?

Some patients treated with this medicine 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.

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 GH

Active ingredient(s): tenofovir disoproxil phosphate

Consumer Medicine Information (CMI)

This leaflet provides important information about using Tenofovir GH. **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 GH.**

Where to find information in this leaflet:

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

1. Why am I using Tenofovir GH?

Tenofovir GH contains the active ingredient tenofovir disoproxil phosphate. Tenofovir GH is a type of medicine called a hepatitis B virus (HBV) polymerase inhibitor and a nucleotide analogue reverse transcriptase inhibitor (NRTI).

Tenofovir GH an antiviral medication is used to treat:

- **Chronic Hepatitis B (an infection with hepatitis B virus [HBV]) in adults and paediatric patients aged 12 years and older and weighing at least 35 kg.**
- **HIV infection in adults and paediatric patients aged 12 years and older and weighing at least 35 kg.** **Tenofovir GH is always used in combination with other anti-HIV medicines to treat people with HIV-1 infection.**

Together with your doctor, you need to decide whether Tenofovir GH is right for you.

Tenofovir GH does not cure HIV infection or AIDS.

The long-term effects of Tenofovir GH are not known at this time. People taking Tenofovir GH 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.

Tenofovir GH 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 use Tenofovir GH?

Warnings

Do not use Tenofovir GH if:

- you are allergic to tenofovir disoproxil phosphate or 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, throat or other parts of the body;
 - rash, itching or hives on the skin.

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

- you are already taking any other medicines that contain the same active ingredients.
- you are already taking adefovir dipivoxil to treat HBV infection.
- you are already taking tenofovir alafenamide to treat HIV or HBV infection.
- the expiry date on the pack has passed.

Check with your doctor if you:

- have any other medical conditions [list any notable ones for the medicine / medical condition here]
- Have, or have had, any other medical conditions, including:
 - kidney problems;
 - bone problems;
 - liver problems including HBV and hepatitis C virus (HCV);
 - HIV-1 infection.
- have allergies to any other medicines, foods, preservatives or dyes.
- 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?](#)

How Tenofovir GH works in the treatment of CHB

Tenofovir GH works by interfering with the normal working of enzymes (HBV DNA polymerase) that are essential for HBV to reproduce itself. Tenofovir GH may help lower the amount of HBV 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 HBV 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 GH may help treat your hepatitis. Sometimes viruses change in your body and medicines no longer work. This is called drug resistance.

How Tenofovir GH works in the treatment of HIV-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 GH helps to block HIV-1 reverse transcriptase, a chemical (enzyme) in your body that is needed for HIV-1 to multiply.

Tenofovir GH lowers the amount of HIV 1 in the blood (called viral load) and may help to increase the number of T 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 GH for HBV and vice versa.

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. The effects of Tenofovir GH on pregnant women or their unborn babies are not known.

Do not breastfeed if you are taking Tenofovir GH. The active substance in this medicine (tenofovir disoproxil) has been found in breast milk at low concentrations.

Do not breastfeed 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 breastfeeding.

Use in Children

Tenofovir GH 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 GH and affect how it works. Tell your doctor or pharmacist if you take:

- Vosevi (sofosbuvir/velpatasvir/voxilaprevir), Harvoni (ledipasvir/sofosbuvir) or Epclusa (sofosbuvir/velpatasvir) to treat your HCV infection. These medicines may increase the amount of tenofovir disoproxil in your blood, which could result in additional or more intense side effects (see

additional information under Section [6. Are there any side effects?](#)).

- Videx, Videx EC (didanosine). Tenofovir GH may increase the amount of didanosine in your blood. Your treatment may need to be followed more carefully if you are taking Videx and Tenofovir GH together. If you are taking Videx and Tenofovir GH 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 disoproxil in your blood, which could result in more side effects (see Section [6. Are there any side effects?](#)). Your treatment may need to be followed more carefully if you are taking Tenofovir GH and Reyataz or Kaletra together. Tenofovir GH may decrease the amount of atazanavir sulfate in your blood. If you are taking Tenofovir GH and Reyataz together you should also be taking Norvir (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 in 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 GH.

4. How do I use Tenofovir GH?

How much to take

- The usual dose of Tenofovir GH is one tablet once a day.
- If you have kidney problems, your doctor may recommend that you take Tenofovir GH less frequently.
- If you are taking Tenofovir GH to treat HIV, or if you have HIV and HBV co-infection and are taking Tenofovir GH, always take Tenofovir GH in combination with other anti-HIV medicines.
- Follow the instructions provided and use Tenofovir GH until your doctor tells you to stop.

When to take Tenofovir GH

- Tenofovir GH 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 Tenofovir GH

- **Do not change your treatment or stop treatment without first talking with your doctor.**
- **When your Tenofovir GH supply starts to run low, get more from your doctor or pharmacist.**

If you forget to use Tenofovir GH

Tenofovir GH should be used regularly at the same time each day. If you miss your dose of Tenofovir GH at the

usual time, take it as soon as possible and then take your next scheduled dose at its regular time.

It is important that you do not miss any doses.

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 you missed.

If you take too much Tenofovir GH

If you think that you have used too much Tenofovir GH, 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 GH?

Things you should do

- **Stay under a doctor's care when taking Tenofovir GH.**
- **Take Tenofovir GH 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.**
- Tenofovir GH and other medicines like Tenofovir GH, may be less likely to work in the future if you are not taking it 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 GH to treat CHB, you are advised to get a HIV test before you start taking Tenofovir GH and at any time after that when there is a chance you were exposed to HIV.
- **If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking this medicine.**

Call your doctor straight away if you:

- become pregnant or plan to breastfeed while taking this medicine.

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

Things you should not do

- **Do not stop using this medicine suddenly, even if for a short period.**
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 GH, and may become harder to treat. If you are taking Tenofovir GH to treat CHB, stopping treatment may result in very severe hepatitis and serious liver problems (see additional information under Section [6. Are there any side effects?](#)).

- Do not breastfeed.
- Only take medicine that has been prescribed specifically for you.
- Do not give Tenofovir GH to others, or take medicine prescribed for someone else, even if they have the same condition as you.
- Do not use this medicine for a condition for which it was not prescribed.
- Do not use if seal over bottle opening is broken or missing.

Driving or using machines

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

Tenofovir GH may cause dizziness in some people.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- Store Tenofovir GH below 25°C.
- Keep your Tenofovir GH tablets in the bottle with the cap tightly closed until you take them. If you take Tenofovir GH tablets out of their pack they may not keep well.

Follow the instructions on 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.

Keep it where young children cannot reach it.

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.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">• Diarrhoea.• Nausea.	Speak to your doctor if you

Less serious side effects	What to do
<ul style="list-style-type: none"> • Vomiting. • Dizziness. • Flatulence (intestinal gas). • Low blood phosphate. • Shortness of breath. • Increased liver enzymes. • Increased amylase. • Inflammation of the liver. • Stomach pain. • Inflammation of the pancreas. • Rash. • Weakness. 	<p>have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p>Kidney Problems</p> <ul style="list-style-type: none"> • Some patients treated with Tenofovir GH 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. <p>Changes in Bone Mineral Density</p> <p>Laboratory tests show changes in the bones of patients treated with Tenofovir GH. It is not known whether long-term use of Tenofovir GH 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.</p> <p>Lactic Acidosis</p> <ul style="list-style-type: none"> • Some patients taking antiviral drugs like Tenofovir GH 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. <p>Hepatic Flares</p> <ul style="list-style-type: none"> • It is extremely important that you do not stop taking Tenofovir GH without your doctor's advice. If 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
<p>you have HBV infection, or HIV and HBV infection together, you may have a "flare-up" of Hepatitis B if you stop taking Tenofovir GH, 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>	

After stopping Tenofovir GH, tell your doctor immediately about any new, unusual, or worsening symptoms that you notice after stopping treatment.

After you stop taking Tenofovir GH, your doctor will still need to check your health and take blood tests to check your liver for several months.

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. 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 GH contains

Active ingredient (main ingredient)	Tenofovir disoproxil phosphate
Other ingredients (inactive ingredients)	Croscarmellose sodium Stearic acid Microcrystalline cellulose OPADRY II complete film-coating system 39K505001 Blue (ARTG 138537)

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

Note: The innovator product contains 300 mg of tenofovir disoproxil fumarate and Tenofovir GH contains 291 mg of tenofovir disoproxil phosphate - 291 mg of tenofovir disoproxil phosphate is equivalent to 300 mg of tenofovir

disoproxil fumarate. Bioequivalence has been established between the two salt forms of tenofovir disoproxil.

What Tenofovir GH looks like

Tenofovir GH is a blue coloured, oval-shaped, biconvex, film-coated tablet debossed on one side with “T1” and plain on other side (AUST R 269193).

Who distributes Tenofovir GH

Generic Health Pty Ltd

Suite 2, Level 2

19-23 Prospect Street

Box Hill, VIC, 3128

Australia

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🌐 www.generichealth.com.au

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