

TENOFOVIR ARX

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 ARX?

Tenofovir ARX contains the active ingredient Tenofovir disoproxil fumarate. Tenofovir ARX is an antiviral medication used to treat CHB and 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 ARX?](#) in the full CMI.

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

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

3. What if I am taking other medicines?

Some medicines may interfere with Tenofovir ARX 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 ARX?

- If you are taking this medicine to treat HIV-1 or if you have HIV-1 and HBV co-infection and are taking this medicine, always take this medicine in combination with other anti-HIV-1 medicines. This medicine and other similar medicines may be less likely to work in the future if you are not taking Tenofovir disoproxil fumarate with other anti-HIV-1 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. More instructions can be found in Section [4. How do I use Tenofovir ARX?](#) in the full CMI.

5. What should I know while using Tenofovir ARX?

| | |
|------------------------------------|---|
| Things you should do | <ul style="list-style-type: none">• Your doctor will tell you how much of this medicine you should take, depending on your condition and whether you are taking any other medicines.• The usual dose is one tablet once a day |
| Things you should not do | <ul style="list-style-type: none">• Do not breastfeed if you are taking Tenofovir ARX.• 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">• Be careful before you drive or use any machines or tools until you know how Tenofovir ARX 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 ARX |
| 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 ARX?](#) 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 ARX

Active ingredient(s): *Tenofovir disoproxil fumarate*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I using Tenofovir ARX?

Tenofovir ARX contains the active ingredient Tenofovir disoproxil fumarate. Tenofovir ARX belongs to a group of medicines called nucleoside analog reverse transcriptase inhibitors (NRTIs)

Chronic Hepatitis B (CHB): Tenofovir ARX is an antiviral medication used to treat CHB in adults and children aged over 12 years and weighing at least 35 kg. Tenofovir ARX works by interfering with the normal working of enzymes that are essential for HBV to reproduce itself. This 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. It 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 this medicine may help treat your hepatitis. Sometimes viruses change in your body and medicines no longer work. This is called drug resistance.

Human Immunodeficiency Virus (HIV-1) Infection:

Tenofovir ARX is also used to treat HIV-1 infection in adults and children aged over 12 years and weighing at least 35 kg. It is always used in combination with other anti-HIV-1 medicines to treat people with HIV-1 infection. HIV-1 infection destroys CD4 (T) cells, which are important to the immune system. After many T cells are destroyed, acquired immune deficiency syndrome (AIDS) develops. This medicine helps to block HIV-1 reverse transcriptase, an enzyme in your body that is needed for HIV-1 to multiply. It 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 infections that happen when your immune system is weak (called opportunistic infections). Tenofovir

ARX does not cure HIV-1 infection or AIDS. You do not have to have HIV-1 infection to be treated with this medicine for HBV and vice versa. Tenofovir ARX 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.

Ask your doctor if you have any questions about why this medicine has been prescribed for you. Your doctor may have prescribed this medicine for another reason. This medicine is available only with a doctor's prescription. This medicine is not addictive. This medicine should not be used in children less than 12 years of age.

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

Warnings

Do not use Tenofovir ARX if:

- you are allergic to Tenofovir disoproxil fumarate, 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 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

Do not take this medicine if you are already taking a combination tablet that contains Tenofovir ARX or are taking adefovir.

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.

Check with your doctor if you:

- have any other medical conditions and/or allergies to any other medicines, foods, preservatives or dyes.
- Tell your doctor if you have or have had any of the following medical conditions:
- kidney problems
 - bone problems
 - liver problems including HBV
 - HIV-1 infection Tell your doctor if you are pregnant or plan to become pregnant.

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

The effects of this medicine on pregnant women or their unborn babies are not known.

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed. Tenofovir ARX has been found in breast milk at low concentrations and may affect your baby. Do not breastfeed if you have HIV-1 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-1 or HBV, there is a chance that the baby can get HIV-1 or HBV through breastfeeding.

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 interact with Tenofovir ARX. These include:

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

If you are taking any of these you may need a different dose or you may need to take different medicines. You may need to be followed more carefully if you are taking these medicines together. Other medicines not listed above may also interact with Tenofovir ARX.

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 ARX.

4. How do I use Tenofovir ARX?

How to use

- If you are taking this medicine to treat HIV-1 or if you have HIV-1 and HBV co-infection and are taking this medicine, always take this medicine in combination with other anti-HIV-1 medicines. This medicine and other similar medicines may be less likely to work in the future if you are not taking Tenofovir disoproxil fumarate with other anti-HIV-1 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 this medicine to treat CHB, you are advised to get a HIV-1 test before you start taking this medicine and at any time after that when there is a chance you were exposed to HIV-1.
- Follow the instructions provided and use Tenofovir ARX until your doctor tells you to stop.

How much to use Tenofovir ARX

Your doctor will tell you how much of this medicine you should take, depending on your condition and whether you are taking any other medicines. The usual dose is one tablet once a day. If you have kidney problems, your doctor may recommend that you take this medicine less frequently.

How to take it

Swallow the tablet whole with water

When to take Tenofovir ARX

Take this 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. It is best taken with a meal or just afterwards.

How long to take it for

Continue taking your medicine for as long as your doctor tells you. Make sure you always have enough supply of Tenofovir ARX. 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 ARX and become harder to treat. If you are taking this medicine to treat CHB, stopping treatment may result in very severe hepatitis and serious liver problem.

If you forget to use Tenofovir ARX

It is important that you do not miss any doses.

Tenofovir ARX should be used regularly at the same time.

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

Otherwise, take it as soon as you remember and then go back to taking your medicine as you would normally

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

This may increase the chance of you experiencing side effects.

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

If you use too much Tenofovir ARX

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

Things you should do

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

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

Call your doctor straight away if you:

- plan to have any vaccinations.
- become pregnant or plan to breastfeed while taking this medicine, tell your doctor immediately.

Keep all your doctor's appointments so that your progress can be checked. Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects.

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

Things you should not do

- Do not breastfeed if you are taking Tenofovir ARX.
- 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.
- Do not stop taking your medicine, or change the dosage, without first checking with your doctor.

It is extremely important that you do not stop taking this medicine without your doctor's advice. If you have a Hepatitis B infection, you may have a 'flare-up', 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 this medicine, tell your doctor immediately about any new, unusual, or worsening symptoms that you notice after stopping treatment. After you stop taking this medicine, your doctor will still need to check your health and take blood tests to check your liver for several months.

Driving or using machines

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

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

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- 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.

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.

Keep it where young children cannot reach it.

When to discard your medicine (as relevant)

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 left over.

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.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

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>Clinical studies in patients with HIV-1:</p> <ul style="list-style-type: none">• diarrhoea• nausea• vomiting• dizziness• flatulence (intestinal gas) <p>Clinical studies in patients with CHB:</p> <p>The only common side effects are:</p> | <p>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.</p> |

| Common side effects | What to do |
|---|--|
| <ul style="list-style-type: none"> nausea <p>Marketing experience: Other side effects reported since this medicine has been marketed include:</p> <ul style="list-style-type: none"> low blood phosphate and potassium shortness of breath increased liver enzymes, increased amylase inflammation of the liver abdominal pain inflammation of the pancreas rash weakness | <p>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.</p> |

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.

Kidney Problems:

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

Effects on Bone:

Laboratory tests show changes in the bones of patients treated with this medicine. It is not known whether long-term use of this medicine 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 this medicine have developed a condition called lactic acidosis. This is 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.

There have been other side effects in patients taking this medicine. 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.

Allergic reactions:

If you think you are having an allergic reaction to Tenofovir disoproxil fumarate, do not take any more of this medicine and tell your doctor immediately or go to the Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all the following:

- 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

Other side effects not listed above may occur in some patients

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 ARX contains

| | |
|---|---|
| Active ingredient (main ingredient) | Each tablet contains 300 mg Tenofovir disoproxil fumarate as the active ingredient. |
| Other ingredients (inactive ingredients) | <ul style="list-style-type: none"> lactose crospovidone calcium stearate colloidal anhydrous silica hypromellose macrogol 8000 hypromellose titanium dioxide indigo carmine aluminium lake |
| Potential allergens | Contains lactose |

This medicine does not contain gluten, sucrose, tartrazine or any other azo dyes. Do not take this medicine if you are allergic to any of these ingredients.

What Tenofovir ARX looks like

Tenofovir ARX is 300 mg tablets: light blue, almond shaped, biconvex, coated tablet. Engraved "TEN" over "300" on one side, "APO" on the other side.

Blister and bottle packs of 30 tablets:

Bottle: AUST R 247315*

Blister: AUST R 247314

* Not all pack types may be available.

Who distributes Tenofovir ARX

Arrotex Pharmaceuticals Pty Ltd

15-17 Chapel Street

Cremorne VIC 3121

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