

Tenofovir APOTEX

Contains the active ingredient tenofovir disoproxil fumarate

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

Read this leaflet carefully before taking your medicine.

This leaflet answers some common questions about tenofovir disoproxil fumarate. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up to date leaflet from www.apotex.com.au.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

It is extremely important that you do not change or stop your medicine without first talking with your doctor.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

What this medicine is used for

The name of your medicine is Tenofovir APOTEX Tablets. It contains the active ingredient tenofovir disoproxil fumarate.

It is an antiviral medication used to treat two different viruses, Chronic Hepatitis B (CHB) and Human Immunodeficiency Virus (HIV) infection.

It is a type of medicine called a HBV polymerase inhibitor and a nucleoside analog reverse transcriptase inhibitor (NRTI).

Use in the Treatment of CHB

Tenofovir disoproxil fumarate 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.

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

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

Use in the Treatment of HIV-Infection

Tenofovir disoproxil fumarate is also used to treat HIV infection in adults and paediatric patients aged 12 years and older and weighing at least 35 kg. It 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.

This medicine helps to block HIV1 reverse transcriptase, a chemical (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 (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 this medicine for HBV and vice versa.

Does this medicine cure HIV-1 or AIDS?

This medicine does not cure HIV-1 infection, or AIDS. The long-term effects of this medicine are not known at this time. People taking this medicine 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 this medicine reduce the risk of passing HIV-1 or HBV to others?

Tenofovir 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.

There is no evidence that this medicine is addictive.

Use in children

This medicine should not be used in children less than 12 years of age.

Before you take this medicine

When you must not take it

Do not take this medicine if:

- **You are already taking a combination tablet that contains tenofovir**
- **You are already taking adenovir dipivoxil**

- **You are hypersensitive to, or have had an allergic reaction to, tenofovir, tenofovir disoproxil fumarate or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may include: cough, 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; fainting; or hay fever-like symptoms.

- **If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.**
- **Your child is taking this medicine and they are less than 12 years of age.**
- The expiry date (EXP) printed on the pack has passed.
- The packaging is torn, shows signs of tampering or it does not look quite right.

Before you start to take it

Before you start taking this medicine, tell your doctor if:

1. You have allergies to:
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
2. You have or have had any medical conditions, especially the following:
 - kidney problems
 - bone problems
 - liver problems including HBV
 - HIV infection
3. You are currently pregnant or you plan to become pregnant.

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

4. You are currently breastfeeding or you plan to breastfeed.

Do not breastfeed if you are taking this medicine. The active substance in this medicine (tenofovir disoproxil fumarate) 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.

5. You have recently been vaccinated or plan to get a vaccination.
6. You are planning to have surgery or an anaesthetic.
7. You are currently receiving or are planning to receive dental treatment.
8. You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Some medicines may interact with tenofovir disoproxil fumarate. These include:

- VIDEX, VIDEX EC (didanosine). This medicine may increase the amount of didanosine in your blood. You may need to be followed more carefully if you are taking these medicines together. Your doctor may need to reduce your dose of didanosine.
- REYATAZ (atazanavir sulfate) or KALETRA (lopinavir/ritonavir). These medicines may increase the amount of tenofovir disoproxil fumarate in your blood, which could result in more side effects. You may need to be followed more carefully if you are taking these medicines together. Tenofovir disoproxil fumarate

may decrease the amount of atazanavir sulfate in your blood. If you are taking tenofovir disoproxil fumarate and atazanavir sulfate together you should also be taking NORVIR (ritonavir).

If you are taking any of these you may need a different dose or you may need to take different medicines.

Other medicines not listed above may also interact with tenofovir.

How to take this medicine

Follow carefully all directions given to you by your doctor. Their instructions may be different to the information in this leaflet.

- If you are taking this medicine to treat HIV or if you have HIV and HBV co-infection and are taking this medicine, always take this medicine in combination with other anti-HIV 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 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 test before you start taking this medicine and at any time after that when there is a chance you were exposed to HIV.
- When your supply of this medicine 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 fumarate, and may become harder to treat. If you are taking this medicine to treat CHB, stopping treatment may result in very severe hepatitis and serious liver problems (see 'Possible side effects').

How much to take

Your doctor will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

Do not stop taking your medicine or change your dosage without first checking with your doctor.

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 tablet with water.

When to take it

Take this medicine at the same time each day. Taking it at the same time each day will have the best effect and 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 have enough to last over weekends and holidays.

If you forget to take it

It is important that you do not miss any doses.

If it is almost time to take your next dose, skip the missed dose and take your next dose at the usual time. 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 missed doses.

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 to help you remember.

If you take too much (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively, go to the Accident and Emergency department at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are taking this medicine

Things you must do

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you plan to have any vaccinations or immunisations
- you are pregnant or are planning to become pregnant
- you are breastfeeding or are planning to breastfeed
- you are about to have any blood tests
- you are going to have surgery or an anaesthetic or are going into hospital.

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects. Go to your doctor regularly for a check-up.

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

Things you must not do

Do not:

- Breastfeed.
- Give this medicine to anyone else, even if their symptoms seem similar to yours.
- Take your medicine to treat any other condition unless your doctor tells you to.
- Stop taking your medicine, or change the dosage, without first checking with your doctor.

Things to be careful of

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.

Possible side effects

Tell your doctor as soon as possible if you do not feel well while you are taking tenofovir disoproxil fumarate or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

Clinical studies in patients with HIV:

The most common side effects are:

- diarrhoea
- nausea
- vomiting,
- dizziness.

Less common side effects include:

- flatulence (intestinal gas).

Clinical studies in patients with CHB:

The only common side effects are:

- nausea
- dizziness

- back pain.

Marketing experience:

Other side effects reported since this medicine has been marketed include:

- allergic reaction
- 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.

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.

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.

Some patients taking antiviral drugs like this medicine 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.

Changes in body fat have been seen in some patients taking anti-HIV medicine. These changes may include increased amount of fat in the upper back and neck ("buffalo

hump"), breast, and around the main part of your body (trunk). Loss of fat from the legs, arms and face may also happen. The cause and long term health effects of these conditions are not known at this time.

It is extremely important that you do not stop taking this medicine 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 this medicine, 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.

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.

Other side effects not listed above may occur in some patients.

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 Accident and Emergency department at your nearest hospital.

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

- cough, 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
- fainting

- hay fever-like symptoms.

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 25°C.

Do not store your medicine, 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 this medicine 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 it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

What Tenofovir APOTEX Tablets looks like

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

Ingredients

Each tablet contains 300 mg tenofovir disoproxil fumarate as the active ingredient.

It also contains the following inactive ingredients:

- lactose

- crospovidone
- calcium stearate
- colloidal anhydrous silica
- hypromellose
- macrogol 8000
- hydroxypropylcellulose
- titanium dioxide
- indigo carmine aluminium lake

This medicine is gluten-free, sucrose-free, tartrazine-free and free of other azo dyes.

Australian Registration Numbers

Tenofovir APOTEX 300 mg Tablets

Bottle: AUST R 247315

Blister: AUST R 247314

* Not all pack types may be available.

Sponsor

Apotex Pty Ltd

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