

Tenofovir/Emtricitabine APOTEX

300/200 Tablets

Tenofovir disoproxil fumarate and emtricitabine

Consumer Medicine Information

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

What is in this leaflet

This leaflet answers some common questions about Tenofovir/Emtricitabine 300/200 APOTEX tablets. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

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.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

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

What this medicine is used for

Tenofovir/Emtricitabine 300/200 consist of both tenofovir and emtricitabine combined into one tablet. This medicine is used:

- to treat Human Immunodeficiency Virus (HIV) infection in adults when taken in combination with other anti-HIV medicines
- to help reduce the risk of getting HIV infection when used with safer sex practices in:
 - HIV-negative men who have sex with men, who are at high risk of getting infected with HIV-

1 through sex.

- Male-female sex partners when one partner has HIV-1 infection and the other does not.

Tenofovir and emtricitabine belong to a group of antiviral medicines known as nucleoside and nucleotide reverse transcriptase inhibitors (NRTI). These medicines help control HIV infection.

Tenofovir/Emtricitabine 300/200 is not a cure for HIV infection or AIDS. While taking this medicine, you may still develop infections or other illnesses associated with HIV infection.

Tenofovir/Emtricitabine 300/200 does NOT reduce the risk of passing HIV to others through sexual contact or blood contamination. It is important to continue to take appropriate precautions to prevent passing HIV to others.

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. Your doctor will generally prescribe Tenofovir/Emtricitabine 300/200 in combination with other anti-HIV medicines.

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

This medicine is not addictive.

There is not enough information to recommend the use of this medicine in children under the age of 18 years.

Before you take this medicine

When you must not take it

Do not take this medicine if you have an allergy to:

- tenofovir disoproxil fumarate
- emtricitabine
- 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

Do not take this medicine if you are already taking the following medicines:

- tenofovir
- emtricitabine
- lamivudine
- adefovir dipivoxil

Do not take this medicine to reduce your risk of getting HIV-1 if you already have HIV-1 or you do not know your infection status.

If you are HIV-positive, you need to take other medicines with Tenofovir/Emtricitabine 300/200 to treat HIV. This medicine by itself is not a complete treatment for HIV.

Tell your doctor if you had a flu-like illness within the last month

before starting this medicine or while taking this medicine.

Many HIV-1 tests can miss HIV-1 infection in a person who has recently become infected. If you have flu-like symptoms, you could have recently become infected with HIV-1. Symptoms of new HIV-1 infection include: tiredness, fever, joint or muscle aches, headache, sore throat, vomiting or diarrhoea, rash, night sweats or enlarged lymph nodes in the neck or groin.

Do not take this medicine after the expiry date printed on the pack or 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 be taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- liver problems including hepatitis B or C virus infection
- kidney problems
- abnormal bones or bone difficulties

Tell your doctor if you are taking medication to treat your hepatitis C virus (HCV) infection (e.g. ledipasvir/sofosbuvir).

Tell your doctor if you are pregnant or plan to become pregnant.

Do not take this medicine whilst pregnant until you and your doctor have discussed the risks and benefits involved. The safe use of Tenofovir/Emtricitabine 300/200 in pregnancy has not been demonstrated. For this reason, it is important that women of child-bearing age use an effective method of contraception to avoid becoming pregnant while taking this medicine.

If you become pregnant while taking this medicine to reduce the risk of

getting HIV-1 infection, talk to your doctor to decide if you should keep taking this medicine.

Tell your doctor if you are breastfeeding.

The active substances in this medicine have been found in breast milk at low concentrations. Therefore, it is recommended that women do not breastfeed during treatment with Tenofovir/Emtricitabine 300/200. In general, women infected with HIV should not breastfeed their infants to avoid transmission of HIV to their newborn infant.

Tell your doctor if you are planning to have surgery, dental treatment or an anaesthetic.

If you have not told your doctor about any of the above, tell them before you start taking this medicine.

Taking other medicines

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

Some medicines and this one may interfere with each other. These include:

- didanosine
- sofosbuvir alone, or in combination with ledipasvir, velpatasvir or voxilaprevir

These medicines may be affected by this medicine or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

Other medicines not listed above may also interact with tenofovir and emtricitabine.

How to take this medicine

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the pack, ask your doctor or pharmacist for help.

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.

The usual dose is one Tenofovir/Emtricitabine 300/200 tablet taken orally once daily.

How to take it

Swallow the tablets whole with a full glass of water.

When to take it

Take your 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.

This medicine is best taken with food, however taking it without food should not reduce the effectiveness of the medicine.

This medicine is absorbed rapidly. Do not take another dose if vomiting has occurred unless it occurs within 1 hour after taking Tenofovir/Emtricitabine 300/200.

How long to take it for

Continue taking your medicine for as long as your doctor tells you.

This medicine helps to control your condition, but does not cure it. It is important to take your medicine every day even if you feel well.

If you are taking this medicine to reduce the risk of HIV-1 infection, take this medicine every day for the

period of time prescribed by your doctor.

Make sure you have enough to last over weekends and holidays.

If you forget to take it

If it is almost time to take 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 that you missed.

This may increase the chance of you experiencing side effects.

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

Do not take more than one Tenofovir/Emtricitabine 300/200 tablet in a day.

Try to avoid missing any doses of your medicine.

Missing a dose lowers the amount of medicine in your blood. If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much of this medicine.

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

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

Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

If you become pregnant while taking this medicine, tell your doctor immediately.

Tell your doctor if you are about to have any blood tests.

Tell your doctor if you are going to have surgery or an anaesthetic or are going into hospital.

Tell your doctor if for any reason you have not taken your medicine exactly as prescribed.

Otherwise your doctor may decide the medication is no longer effective.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may occasionally arrange tests to make sure the medicine is working and to prevent unwanted side effects.

Things you must not do

Do not take your medicine to treat any other complaints unless your doctor tells you to.

Do not give this medicine to anyone else, even if they have the same condition as you.

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

Things to be careful of

Be careful driving or operating machinery until you know how this medicine affects you.

This medicine may cause dizziness or tiredness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Talk to your doctor about how to reduce the risk of spreading HIV-1 to other people.

You can reduce the risk of spreading HIV-1 to other people by:

- not having any kind of sex without protection. Always practice safer sex. Use latex or non-latex condoms (except

lambskin) to reduce contact with semen, vaginal fluids, or blood.

- not sharing personal items that can have blood or body fluids on them, such as toothbrushes and razor blades.
- not sharing or re-using needles or other injection equipment.

If you are taking this medicine to reduce your risk of getting HIV, you should also take other steps to reduce your risk. This includes:

- continue using safer sex practices
- get information and support to help reduce risky sexual behaviour
- have fewer sex partners
- know your HIV status and the HIV status of your partners
- get tested for HIV at least every 3 months or when your healthcare provider tells you
- get tested for other sexually transmitted infections such as syphilis and gonorrhoea. These infections make it easier for HIV to infect you. This medicine will not stop you from getting these other infections
- do not miss any doses of your medicine. Missing doses may increase your risk of getting HIV infection.

If you are taking this medicine to reduce your risk of getting HIV and you think you were exposed to HIV, tell your healthcare provider right away. They may want to do more tests to be sure you are still HIV-negative.

You must stay HIV-negative to keep taking this medicine to reduce your risk of infection. If you do become HIV-positive, you need more medicine than Tenofovir/Emtricitabine 300/200 alone to treat HIV. This medicine by itself is not a complete treatment for HIV. If you have HIV and take only this medicine, over time your HIV may become harder to treat.

Tenofovir/Emtricitabine 300/200 can only be prescribed by a doctor

who specialises in the treatment of HIV infection.

If you wish to continue receiving this medicine, it is important you remain under the care of a hospital or doctor who specialises in the treatment of HIV infection.

If you have a long standing viral infection of your liver (hepatitis B), it may flare up when you stop taking this medicine.

This can cause serious illness particularly if your liver is already not working very well. If you have both HIV and hepatitis B, your doctor will arrange tests before and during treatment to check how well your liver is working.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking this medicine.

This medicine helps most people, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

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

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- stomach complaints, such as diarrhoea, nausea, abdominal pain
- tiredness
- headache
- dizziness
- depression
- difficulty sleeping, abnormal dreams
- skin rash
- decreased weight.

Tell your doctor as soon as possible if you notice any of the following:

- changes in body fat, such as an increased amount of fat in the upper back and neck ("buffalo hump"), in the breasts and around the trunk. Loss of fat from the legs, arms and face may also happen.
- Some patients treated with tenofovir disoproxil fumarate 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 healthcare provider may need to perform additional blood tests.
- bone pain, or softening or thinning of bones, which may lead to fractures. Your doctor may need to do tests to check your bones.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- severe stomach pain or cramps, severe nausea or vomiting (signs of pancreatitis)
- yellowing of skin or white part of your eyes, dark urine, light-coloured stools, loss of appetite, nausea, stomach pains (signs of serious liver problems or hepatotoxicity)
- 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 (symptoms of an allergic reaction)
- sign and symptoms of inflammation or infection, such as fever or chills. This may occur soon after starting your medicine. It is believed that these symptoms are due to an improvement in the body's immune response, which lets the body fight infections that may have been present with no obvious symptoms of infection.
- feeling very weak or tired, unusual muscle pain, trouble breathing, stomach pain with nausea and vomiting, feeling cold

especially in your arms and legs, dizziness or light-headedness, fast or irregular heartbeat (signs of lactic acidosis).

You may be more likely to get lactic acidosis or liver problems if you are female, very overweight (obese), or have been taking similar anti-viral therapies for a long time.

The above list includes very serious side effects and you may need urgent medical attention.

Hepatic Flares

Your doctor should test you to see if you have chronic hepatitis B infection before you start taking Tenofovir/Emtricitabine 300/200.

If you have HIV infection and chronic hepatitis B infection you should not stop taking this medicine without first discussing this with your doctor, as some patients have had blood tests or symptoms indicating a worsening of their hepatitis ("hepatic flare") after stopping tenofovir or emtricitabine.

You may require medical exams and blood tests for several months after stopping treatment.

Tenofovir/Emtricitabine 300/200 is not approved for the treatment of hepatitis B, so you must discuss your hepatitis B therapy with your doctor.

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

Storage and disposal

Storage

Keep your tablets in the pack until it is time to take them.

If you take your medicine out of the pack it may not keep well.

Keep your medicine in a cool dry place where the temperature stays 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, ask your pharmacist what to do with any medicine left over.

Tel: (02) 8877 8333

Web: www1.apotex.com/au

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Product description

What it looks like

300 mg/200 mg tablet: Blue, capsule-shaped, biconvex coated tablet.

Engraved "APO" on one side "E-T" on the other side.

Blister packs (30 tablets): AUST R 275070

Bottles (30 tablets): AUST R 275071

* Not all pack types may be available.

Ingredients

Each tablet contains 300 mg of tenofovir disoproxil fumarate and 200 mg of emtricitabine as the active ingredients.

It also contains the following:

- colloidal anhydrous silica
- crospovidone
- magnesium stearate
- lactose

Film coating:

- macrogol 8000
- purified talc
- titanium dioxide
- indigo Carmine Aluminium Lake
- polyvinyl alcohol

This medicine does not contain gluten, sucrose, tartrazine or any other azo dyes.

Sponsor

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