

Tenofovir disoproxil / Emtricitabine film coated tablet 300mg/200mg

What is in this leaflet

Please read this leaflet carefully before you start taking Tenofovir Disoproxil Emtricitabine Mylan.

This leaflet answers some common questions about Tenofovir Disoproxil Emtricitabine Mylan.

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 taking Tenofovir Disoproxil Emtricitabine Mylan 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 need to read it again.

What Tenofovir Disoproxil Emtricitabine Mylan is used for

Tenofovir Disoproxil Emtricitabine Mylan is used to:

- Treat Human Immunodeficiency Virus-1 (HIV-1) infection in adults when taken in combination with other anti-HIV medicines.
- 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.

When Tenofovir Disoproxil Emtricitabine Mylan is used to treat HIV infection

When used with other HIV-1 medicines to treat HIV-1 infection, Tenofovir Disoproxil Emtricitabine Mylan may help:

- Reduce the amount of HIV-1 in your blood. This is called “viral load”.
- Increase the number of CD4+ (T) cells in your blood that help fight off other infections.

Reducing the amount of HIV-1 and increasing the CD4+ (T) cells in your blood may help improve your immune system.

This may reduce your risk of death or infections that can happen when your immune system is weak.

This medicine belongs to a group of antiviral medicines known as nucleoside and nucleoside reverse transcriptase inhibitors (NRTI).

Tenofovir Disoproxil Emtricitabine Mylan contains the active ingredient tenofovir disoproxil maleate and emtricitabine.

The two active ingredients are combined in one tablet to help control HIV infection.

Your doctor may have prescribed this medicine for another reason.

Use in children and elderly

Tenofovir Disoproxil Emtricitabine Mylan is for adults.

Do not take Tenofovir Disoproxil

Emtricitabine Mylan if you are under the age of 18 years.

Do not take Tenofovir Disoproxil Emtricitabine Mylan if you are over the age of 65 before discussing with your doctor.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

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

Does Tenofovir Disoproxil Emtricitabine Mylan cure HIV or AIDS

Tenofovir Disoproxil Emtricitabine Mylan is not a cure for HIV infection or AIDS. While taking Tenofovir Disoproxil Emtricitabine Mylan you may still develop infections or other illnesses associated with HIV infection.

If you have HIV-1 infection, you must keep taking HIV-1 medicines to control HIV-1 infection and decrease HIV-related illnesses.

Does Tenofovir Disoproxil Emtricitabine Mylan reduce the risk of passing HIV to others

Tenofovir Disoproxil Emtricitabine Mylan 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.

When Tenofovir Disoproxil Emtricitabine Mylan is used to reduce the risk of HIV infection

When used with safer sex practices, Tenofovir Disoproxil Emtricitabine Mylan may help to reduce the risk of getting HIV-1 infection.

Tenofovir Disoproxil Emtricitabine Mylan works better to reduce the risk of getting HIV-1 when the medicines are in your bloodstream **before** you are exposed to HIV-1.

Before you take Tenofovir Disoproxil Emtricitabine Mylan

When you must not take it

Do not take Tenofovir Disoproxil Emtricitabine Mylan if you have an allergy to:

- any medicine containing tenofovir, 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 or other parts of the body; rash, itching or hives on the skin.

Do not take Tenofovir Disoproxil Emtricitabine Mylan if you are already taking any of the components of Tenofovir Disoproxil Emtricitabine Mylan (tenofovir or emtricitabine).

Do not take Tenofovir Disoproxil Emtricitabine Mylan if you are taking lamivudine.

Do not take Tenofovir Disoproxil Emtricitabine Mylan if you are taking adefovir dipivoxil.

Do not take Tenofovir Disoproxil Emtricitabine Mylan if you are taking tenofovir alafenamide.

Do not give this medicine to a child under the age of 18 years. Safety and effectiveness in children

younger than 18 years have not been established.

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.

For people using Tenofovir Disoproxil Emtricitabine Mylan to reduce the risk of getting HIV-1 infection:

Tenofovir Disoproxil Emtricitabine Mylan can only help reduce your risk of getting HIV-1 before you are infected.

Do not take Tenofovir Disoproxil Emtricitabine Mylan to help reduce your risk of getting HIV-1 if:

- you already have HIV-1 infection. If you are HIV-positive, you need to take other medicines with Tenofovir Disoproxil Emtricitabine Mylan to treat HIV. Tenofovir Disoproxil Emtricitabine Mylan by itself is not a complete treatment for HIV.
- you do not know your HIV-1 infection status. You may already be HIV-positive. You need to take other HIV-1 medicines with Tenofovir Disoproxil Emtricitabine Mylan to treat HIV-1.
- 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. Tell your healthcare provider if you had a flu-like illness within the last month before starting Tenofovir Disoproxil Emtricitabine

Mylan or at any time while taking Tenofovir Disoproxil Emtricitabine Mylan. Symptoms of new HIV-1 infection include: tiredness, fever, joint or muscle aches, headache, sore throat, vomiting or diarrhoea, rash, nightsweats or enlarged lymph nodes in the neck or groin.

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:

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding. Your doctor can discuss with you the risks and benefits involved.

The safe use of Tenofovir Disoproxil Emtricitabine Mylan in pregnancy has not been demonstrated. For this reason, it is important that women of child-bearing age receiving treatment with Tenofovir Disoproxil Emtricitabine Mylan use an effective method of contraception to avoid becoming pregnant.

If you are a female who is taking Tenofovir Disoproxil Emtricitabine Mylan to reduce the risk of getting HIV-1 infection and you become pregnant while taking Tenofovir Disoproxil Emtricitabine Mylan, talk to your healthcare provider to decide if you should keep taking Tenofovir Disoproxil Emtricitabine Mylan.

The active substances in this medicine (tenofovir disoproxil fumarate and emtricitabine) have been found in breastmilk at low concentrations.

Consequently, it is recommended that nursing mothers do not breast-feed during treatment with Tenofovir Disoproxil Emtricitabine Mylan. In general, women infected with HIV should not breast-feed their infants in order to avoid transmission of HIV to their newborn infant.

Tell your doctor if you have liver problems, including hepatitis B, or Cvirus infection.

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

Tell your doctor if you have kidney problems.

Tell your doctor if you have or have ever had abnormal bones or bone difficulties.

This medicine is only available from a pharmacist after it has been prescribed by a doctor who specialises in the treatment of HIV infection.

If you wish to continue receiving treatment with Tenofovir Disoproxil Emtricitabine Mylan it is important you remain under the care of a hospital or doctor who specialises in the treatment of HIV infection.

Avoid doing things that increase your risk of getting HIV-1 or spreading HIV-1 to other people:

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

Ask your healthcare provider if you have any questions about how to prevent getting HIV-1 or spreading HIV-1 to other people.

If you have a long standing viral infection of your liver (hepatitis B) it may flare up when you stop taking Tenofovir Disoproxil Emtricitabine Mylan.

This can cause serious illness particularly if your liver is already not working very well. If you have both HIV and hepatitis B, when you start taking Tenofovir Disoproxil Emtricitabine Mylan and even after you stop, your doctor is likely to arrange tests from time to time to check how well your liver is working.

If you have not told your doctor about any of the above, tell them before you start taking Tenofovir Disoproxil Emtricitabine Mylan.

Taking other medicines

If you have HIV infection your doctor will generally prescribe Tenofovir Disoproxil Emtricitabine Mylan in combination with other anti-HIV medicines.

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

You should also tell any health professional who is prescribing a new medication for you that you are taking Tenofovir Disoproxil Emtricitabine Mylan.

Some medicines may interfere with Tenofovir Disoproxil Emtricitabine Mylan. These include:

- Didanosine
- Ledipasvir/sofosbuvir
- Sofosbuvir/velpatasvir
- Sofosbuvir/velpatasvir/voxilaprevir

These medicines may be affected by Tenofovir Disoproxil Emtricitabine Mylan 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.

How to take Tenofovir Disoproxil Emtricitabine Mylan

Take Tenofovir Disoproxil Emtricitabine Mylan exactly as prescribed. The usual dose is one Tenofovir Disoproxil Emtricitabine Mylan tablet orally once daily. Take Tenofovir Disoproxil Emtricitabine Mylan at the same time each day to keep Tenofovir Disoproxil Emtricitabine Mylan blood levels constant.

Tenofovir Disoproxil Emtricitabine Mylan is best taken with a meal or just afterwards, however taking it without food should not reduce the effectiveness of the medicine.

Tenofovir Disoproxil Emtricitabine Mylan is absorbed rapidly. Do not take another Tenofovir Disoproxil Emtricitabine Mylan dose if vomiting has occurred unless it occurs within 1 hour after taking Tenofovir Disoproxil Emtricitabine Mylan.

Always take the dose recommended by your doctor to ensure that your medicine is fully effective and to reduce the development of drug resistance.

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

How much to take

Take one Tenofovir Disoproxil Emtricitabine Mylan tablet once daily or as advised by your doctor.

If you are not sure how much Tenofovir Disoproxil Emtricitabine Mylan you should take, check with your doctor or pharmacist. Do not change the amount of Tenofovir Disoproxil Emtricitabine Mylan you take unless told to do so by your doctor.

Your doctor will tell you how much Tenofovir Disoproxil Emtricitabine Mylan to take and how often to take it. You will also find this information

on the label of your medicine container.

Because your medicine helps to control your condition, but does not cure it you will need to take Tenofovir Disoproxil Emtricitabine Mylan every day.

If you are taking Tenofovir Disoproxil Emtricitabine Mylan to reduce the risk of HIV-1 infection, take Tenofovir Disoproxil Emtricitabine Mylan every day for the period of time as prescribed by your doctor.

Do not miss any doses of Tenofovir Disoproxil Emtricitabine Mylan. Missing a dose lowers the amount of medicine in your blood.

Do not stop taking Tenofovir Disoproxil Emtricitabine Mylan without first talking to your doctor.

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.

It does not matter if you take this medicine before or after food.

How long to take it

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 keep taking your medicine even if you feel well.

Continue taking your medicine until you finish the pack.

If you forget to take it

It is important to take the prescribed daily dose in order to get the maximum benefit of treatment.

If you forget to take your daily dose of Tenofovir Disoproxil Emtricitabine

Mylan, take it as soon as you remember that day, 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.

Do not take more than one Tenofovir Disoproxil Emtricitabine Mylan tablet in a day.

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

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

While you are taking Tenofovir Disoproxil Emtricitabine Mylan

Things you must do

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

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

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery.

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

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

If you are about to have any blood tests, tell your doctor that you are taking this medicine. It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked. Your doctor may do some tests from time to time to make sure the

medicine is working and to prevent unwanted side effects.

If you are taking Tenofovir Disoproxil Emtricitabine Mylan to reduce your risk of getting HIV

Just taking Tenofovir Disoproxil Emtricitabine Mylan may not keep you from getting HIV.

You must continue using safer sex practices while you are taking Tenofovir Disoproxil Emtricitabine Mylan to reduce your risk of getting HIV.

You must stay HIV-negative to keep taking Tenofovir Disoproxil Emtricitabine Mylan to reduce your risk of infection.

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.

Tenofovir Disoproxil Emtricitabine Mylan will not stop you from getting these other infections.

If 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.

Get information and support to help reduce risky sexual behaviour.

Have fewer sex partners.

Do not miss any doses of Tenofovir Disoproxil Emtricitabine Mylan. Missing doses may increase your risk of getting HIV infection.

If you do become HIV-positive, you need more medicine than Tenofovir Disoproxil Emtricitabine Mylan alone to treat HIV. Tenofovir Disoproxil Emtricitabine Mylan by itself is not a complete treatment for HIV.

If you have HIV and take only Tenofovir Disoproxil Emtricitabine Mylan, over time your HIV may become harder to treat.

Things you must not do

Do not take Tenofovir Disoproxil Emtricitabine Mylan to treat any other complaints unless your doctor tells you to.

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

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

If you stop taking it suddenly, your condition may worsen or you may have unwanted side effects.

If possible, your doctor will gradually reduce the amount you take each day before stopping the medicine completely.

Do not use Tenofovir Disoproxil Emtricitabine Mylan to treat any other complaints unless your doctor says so.

Things to be careful of

Be careful driving or operating machinery until you know how Tenofovir Disoproxil Emtricitabine Mylan affects you. This medicine may cause dizziness in some people. If you have any of the symptom, do not drive, operate machinery or do anything else that could be dangerous.

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

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly. Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to

accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much Tenofovir Disoproxil Emtricitabine Mylan. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Tenofovir Disoproxil Emtricitabine Mylan

This medicine helps most people with HIV-1 infection, 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 treatment if you get some of the side effects.

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

The most common side effects in people taking Tenofovir Disoproxil Emtricitabine Mylan to treat HIV-1 infection include:

- diarrhoea
- nausea
- tiredness
- headache
- dizziness
- depression
- problems sleeping
- abnormal dream
- rash

Common side effects in people who take Tenofovir Disoproxil Emtricitabine Mylan to reduce the risk of getting HIV-1 infection include:

- stomach-area (abdomen) pain
- headache
- decreased weight

Ask your doctor or pharmacist to

answer any question you may have about these or other effects.

Allergy

Some people are allergic to medicines.

If you have any of the following symptoms soon after taking your medicine, DO NOT TAKE ANY MORE Tenofovir Disoproxil Emtricitabine Mylan and tell your doctor IMMEDIATELY or go to the accident and emergency department at your nearest hospital:

- Skin troubles such as lumpy skin rash or "hives"
- Swelling of the face, lips mouth or throat which may cause difficulty in swallowing or breathing
- Wheezing, chest pain or tightness
- Fainting

These are very serious effects. If you have them, you may have a serious allergic reaction. You may need urgent medical attention or hospitalisation. All of these side effects are very rare.

Pancreatitis

If you have any of the following symptoms after starting your medication, tell your doctor IMMEDIATELY or go to the accident and emergency department at your nearest hospital:

- Severe stomach pain or cramps
- Nausea
- Vomiting

These side effects may be due to a condition called pancreatitis which sometimes occurs in patients taking anti-HIV medicines.

Serious liver problems (hepatotoxicity)

If you have any of the following symptoms after starting your medication, tell your doctor IMMEDIATELY or go to the accident and emergency

department at your nearest hospital:

- Your skin or the white part of your eyes turns yellow (jaundice)
- Your urine turns dark
- Your bowel movements (stools) turn light in colour
- you don't feel like eating food for several days or longer
 - Nausea
 - Stomach-area pains

These side effects may be due to a condition called hepatotoxicity with liver enlargement and fat deposits in the liver (steatosis) which sometimes occurs in patients taking anti-HIV medicines

Lactic acidosis

If you have any of the following symptoms after starting your medication, tell your doctor IMMEDIATELY or go to the accident and emergency department at your nearest hospital:

- You feel very weak or tired
- You have unusual (not normal) muscle pain
- You have trouble breathing
- You have stomach pain with nausea and vomiting
- You feel cold, especially in your arms and legs
- You feel dizzy or light headed
- You have a fast or irregular heartbeat

These side effects may be due to a condition called lactic acidosis (build-up of an acid in the blood).

Lactic acidosis can be a medical emergency and may need to be treated in the hospital.

You may be more likely to get lactic acidosis or liver problems if you are female, very overweight (obese), or have been taking similar nucleoside analog-containing medicines, like Tenofovir Disoproxil Emtricitabine Mylan, for a long time.

Hepatic Flares

Your doctor should test you to see if you have chronic hepatitis B infection before you start taking Tenofovir Disoproxil Emtricitabine Mylan.

If you have chronic hepatitis B infection you should not stop your Tenofovir Disoproxil Emtricitabine Mylan treatment 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 individual components (tenofovir disoproxil fumarate and emtricitabine) of Tenofovir Disoproxil Emtricitabine Mylan.

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

Tenofovir Disoproxil Emtricitabine Mylan is not approved for the treatment of hepatitis B, so you must discuss your hepatitis B therapy with your healthcare provider.

Other possible side effects:

This list of side effects is not complete.

Tenofovir Disoproxil Emtricitabine Mylan may cause other serious side effects.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list:

New and worse 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 to check your kidneys

Bone problems

Bone problems can happen in some people who take Tenofovir Disoproxil Emtricitabine Mylan. Bone problems include bone pain, or softening or thinning of bones, which may lead to fractures. Your healthcare provider may need to do tests to check your bones.

Signs and symptoms of inflammation

In some patients with advanced HIV infection (AIDS), signs and symptoms of inflammation from previous infections may occur soon after anti-HIV treatment is started. 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. If you notice any symptoms of infection, please tell your doctor immediately.

Some people may get other side effects while taking Tenofovir Disoproxil Emtricitabine Mylan. If you are concerned, talk to your doctor or pharmacist.

Ask your doctor or pharmacist if you don't understand anything in this list.

Do not be alarmed by this list of possible side-effects. Most of them are very rare and you may not experience any of them.

After taking Tenofovir Disoproxil Emtricitabine Mylan

Storage

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

If you take the tablets out of the bottle they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 25°C.

Do not store taking Tenofovir Disoproxil Emtricitabine Mylan 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 it 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 the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

www.viatris.co.nz
Telephone 0800 168 169

Date of Preparation

9 May 2022.
(Based on datasheet dated 9 May 2022)

Product description

What it looks like

A light green, film-coated, capsule shaped, biconvex tablet debossed with 'M' on one side of the tablet and 'ETM' on the other side.

Ingredients

Active ingredients:

Tenofovir Disoproxil Emtricitabine Mylan contains 300 mg of tenofovir disoproxil maleate (equivalent to 245 mg tenofovir disoproxil) and 200 mg of emtricitabine as the active ingredients.

Inactive ingredients:

Tenofovir Disoproxil Emtricitabine Mylan also contains:

- microcrystalline cellulose
- ferric oxide red
- lactose monohydrate
- hydroxypropyl cellulose
- silica colloidal anhydrous
- magnesium stearate
- hypromellose
- titanium dioxide
- triacetin
- FD & C Blue No. 1
- iron oxide yellow

Contains lactose.

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine

Tenofovir Disoproxil Emtricitabine Mylan is supplied in New Zealand by:

Viatis Ltd
PO Box 11-183
Ellerslie
AUCKLAND