

TENOFOVIR EMT GH

(tenofovir disoproxil phosphate and emtricitabine) film-coated tablet

Consumer Medicine Information

What is in this leaflet

Read all of this leaflet carefully before you start taking this medicine.

This leaflet answers some of the common questions about Tenofovir EMT GH. It does not contain all of the available information.

It does not take the place of talking to your doctor or pharmacist about your medical condition or treatment. If you have further questions, please ask your doctor or your pharmacist.

Keep this leaflet with your Tenofovir EMT GH medicine.

You may need to read it again.

What Tenofovir EMT GH is used for

Tenofovir EMT GH is used to treat Human Immunodeficiency Virus (HIV) infection in adults. This medicine must be taken in combination with other anti-HIV medicines.

Tenofovir EMT GH contains two active ingredients that belong to a group of antiviral medicines known as nucleoside and nucleotide reverse transcriptase inhibitors (NRTI).

Tenofovir EMT GH is used:

- to treat Human Immunodeficiency Virus-1 (HIV-1) 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; and
 - Male-female sex partners when one partner has HIV-1 infection and the other does not.

When Tenofovir EMT GH is used to treat HIV infection

When used with other HIV-1 medicines to treat HIV-1 infection, Tenofovir EMT GH 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.

Use in Children and Elderly

Tenofovir EMT GH is for adults.

Do not take Tenofovir EMT GH if you are under the age of 18 years.

Do not take Tenofovir EMT GH if you are over the age of 65 before discussing with your doctor.

Does Tenofovir EMT GH cure HIV or AIDS

Tenofovir EMT GH is not a cure for HIV infection or AIDS. While taking Tenofovir EMT GH 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 EMT GH reduce the risk of passing HIV to others

Tenofovir EMT GH 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 EMT GH is used to reduce the risk of HIV infection

When used with safer sex practices, Tenofovir EMT GH may help to reduce the risk of getting HIV-1 infection if you are at high risk of getting HIV infection.

Tenofovir EMT GH reduces the risk of getting HIV-1 when you have been taking it **before** you are exposed to HIV-1.

Before you take Tenofovir EMT GH

When you must not take it

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

Do not take Tenofovir EMT GH if you are allergic to:

- tenofovir;
- tenofovir disoproxil phosphate;
- any of the other ingredients of Tenofovir EMT GH.

Some of the symptoms of an allergic reaction may include:

- shortness of breath;
- wheezing or difficulty breathing;
- rash, itching or hives on the skin;
- swelling of the face, lips, tongue or other parts of the body.

The ingredients of Tenofovir EMT GH are listed in the 'Product Description' section of this leaflet.

Do not take Tenofovir EMT GH if you are already taking any of the components of Tenofovir EMT GH (tenofovir disoproxil phosphate or emtricitabine).

Do not take Tenofovir EMT GH if you are taking lamivudine.

Do not take Tenofovir EMT GH if you are taking adefovir dipivoxil.

Do not take Tenofovir EMT GH if you are taking tenofovir alafenamide.

Do not take Tenofovir EMT GH after the expiry or "use by" date (EXP) printed on the bottle.

If you take it after the expiry date has passed, it may not work as well.

Do not take Tenofovir EMT GH if the packaging is torn or shows signs of tampering.

If you are not sure whether you should be taking Tenofovir EMT GH, talk to your doctor.

For people using Tenofovir EMT GH to reduce the risk of getting HIV-1 infection
Tenofovir EMT GH can only help reduce your risk of getting HIV-1 before you are infected.

Do not take Tenofovir EMT GH 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 EMT GH to treat HIV. Tenofovir EMT GH 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 EMT GH to treat HIV-1.
- you have had recent flu-like symptoms. 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 EMT GH or at any time while taking Tenofovir EMT GH. 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.

Before you start to take it

Tell your doctor if you are allergic to foods, dyes, preservatives or any other medicines.

Tell your doctor if you are pregnant, trying to become pregnant or breastfeeding.

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

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

The active substances in the innovator medicine, TRUVADA (tenofovir disoproxil fumarate and emtricitabine), have been found in breast milk at low concentrations.

Consequently, it is recommended that nursing mothers do not breast-feed during treatment with Tenofovir EMT GH. 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 C virus infection.

Tell your doctor if you are taking medication to treat your hepatitis C virus (HCV) infection (eg. 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 EMT GH 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 safe 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 EMT GH.

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 EMT GH and even after you stop, your doctor is likely to arrange tests from time to time to check how well your liver is working.

Taking other medicines

If you have HIV infection, your doctor will generally prescribe Tenofovir EMT GH in combination with other anti-HIV medicines.

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

Tell your doctor if are taking:

- didanosine (also known as ddI or Videx);
- ledipasvir/ sofosbuvir (HARVONI);
- sofosbuvir/velpatasvir (EPCLUSA);
- sofosbuvir/ velpatasvir/ voxilaprevir (eg. VOSEVI).

Some medicines may affect the way others work. Your doctor or pharmacist will be able to tell you what to do when taking Tenofovir EMT GH tablets with other medicines.

How to take Tenofovir EMT GH

Take Tenofovir EMT GH exactly as prescribed. The usual dose is one (1) Tenofovir EMT GH tablet taken orally once daily. Take Tenofovir EMT GH at the same time each day to keep Tenofovir EMT GH blood levels constant.

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

Tenofovir EMT GH is absorbed rapidly. Do not take another Tenofovir EMT GH dose if vomiting has occurred unless it occurs within one (1) hour after taking Tenofovir EMT GH.

How much to take

Take one Tenofovir EMT GH tablet once daily or as advised by your doctor.

If you are not sure how much Tenofovir EMT GH you should take, check with your

doctor or pharmacist. Do not change the amount of Tenofovir EMT GH you take unless told to do so by your doctor.

Your doctor will tell you how much Tenofovir EMT GH 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 EMT GH every day. If you are taking Tenofovir EMT GH to reduce the risk of HIV-1 infection, take Tenofovir EMT GH every day for the period of time as prescribed by your doctor.

Do not miss any doses of Tenofovir EMT GH. Missing a dose lowers the amount of medicine in your blood.

Do not stop taking Tenofovir EMT GH without first talking to your doctor.

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 EMT GH, 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 a forgotten dose.

Do not take more than one Tenofovir EMT GH tablet in a day.

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26), or go to the Accident and Emergency department at your nearest hospital if you think you or anyone else may have taken too many Tenofovir EMT GH tablets. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are taking Tenofovir EMT GH

Things you must do

Tell your doctor or pharmacist that you are taking Tenofovir EMT GH if you are about to be started on any other medicines.

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

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

If you are taking Tenofovir EMT GH to reduce your risk of getting HIV

Just taking Tenofovir EMT GH may not keep you from getting HIV.

You must continue using safe sex practices while you are taking Tenofovir EMT GH to reduce your risk of getting HIV.

You must stay HIV-negative to keep taking Tenofovir EMT GH to reduce your risk of infection.

Know your HIV status and the HIV status of your partners.

Get tested for HIV at least every three (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 EMT GH 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 EMT GH. Missing doses may increase your risk of getting HIV infection.

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

If you have HIV and take only Tenofovir EMT GH, over time your HIV may become harder to treat.

Things you must not do

Do not stop taking Tenofovir EMT GH or change the dose without first checking with your doctor.

Do not give this medicine to anyone else even if their symptoms seem similar to yours.

Do not use Tenofovir EMT GH 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 EMT GH affects you.

Side effects

Like all medicines, Tenofovir EMT GH can have side effects, although not everybody gets them. Some may be serious and need medical attention.

Check with your doctor as soon as possible if you have any problems while taking Tenofovir EMT GH, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

The most common side effects in people taking Tenofovir EMT GH to treat HIV-1 infection include:

- diarrhoea;
- nausea;
- tiredness;
- headache;
- dizziness;
- depression;
- problems sleeping;
- abnormal dreams;
- rash.

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

- stomach-area (abdominal) 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 EMT GH 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 while taking 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 taking 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 analogue-containing medicines, like Tenofovir EMT GH, 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 EMT GH.

If you have chronic hepatitis B infection you should not stop your Tenofovir EMT GH 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 the innovator product Truvada.

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

Tenofovir EMT GH 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 EMT GH 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 EMT GH. 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 EMT GH. 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 EMT GH

Storage

Keep Tenofovir EMT GH tablets where children cannot reach them.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store them.

Keep Tenofovir EMT GH tablets in a cool, dry place where it stays below 25°C.

Do not store Tenofovir EMT GH or any other medicine in a bathroom or near a sink.

Do not leave Tenofovir EMT GH in the car or on a window sill.

Heat and dampness can destroy some medicines.

Keep your Tenofovir EMT GH tablets in the bottle with the cap tightly closed until you take them.

If you take Tenofovir EMT GH tablets out of their pack they may not keep well.

Disposal

If your doctor tells you to stop taking Tenofovir EMT GH, or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets left over.

Product description

What it looks like

Tenofovir EMT GH tablets are oval-shaped and blue in colour and are plain on both sides.

Tenofovir EMT GH tablets are supplied in bottles containing 30 and 100 tablets with a child resistant closure.

Not all pack sizes may be marketed.

Ingredients

Active ingredient

Each Tenofovir EMT GH tablet contains the following active ingredients:

- 291 mg tenofovir disoproxil phosphate (which is equivalent to 245 mg of tenofovir disoproxil);
- 200 mg emtricitabine.

Note: The innovator product contains 300 mg of tenofovir disoproxil fumarate and 200 mg of emtricitabine. 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.

Other ingredients

- croscarmellose sodium;
- microcrystalline cellulose;
- mannitol;
- colloidal anhydrous silica;
- stearic acid.

The tablet film-coating (OPADRY II complete film coating system 39K505001 Blue [PI 138537]) contains the following ingredients:

- triacetin;
- hypromellose;
- indigo carmine aluminium lake;
- lactose monohydrate;
- titanium dioxide.

Australian Registration Numbers

Tenofovir EMT GH: AUST R 269196.

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