

TRUVADA[®] Tablets

300 mg tenofovir disoproxil fumarate / 200 mg emtricitabine

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 TRUVADA tablets. 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 TRUVADA medicine. You may need to read it again.

What is TRUVADA

How TRUVADA works

TRUVADA consists of two medicines combined in one tablet:

- tenofovir disoproxil fumarate, also called tenofovir DF
- emtricitabine or FTC

These are combined in one tablet to help control Human Immunodeficiency Virus (HIV) infection.

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

What is TRUVADA used for

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

When TRUVADA is used to treat HIV infection

When used with other HIV-1 medicines to treat HIV-1 infection, TRUVADA 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

TRUVADA is for adults.

Do not take TRUVADA if you are under the age of 18 years.

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

Does TRUVADA cure HIV OR AIDS

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

TRUVADA 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 TRUVADA is used to reduce the risk of HIV infection

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

TRUVADA 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 TRUVADA

Who must not take it

Together with your doctor, you need to decide whether TRUVADA is right for you.

Do not take TRUVADA if you are allergic to:

- tenofovir
- tenofovir DF
- any of the other ingredients of TRUVADA

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 TRUVADA are listed in the product description section of this leaflet.

Do not take TRUVADA if you are already taking any of the components of TRUVADA (tenofovir DF or emtricitabine).

Do not take TRUVADA if you are taking lamivudine.

Do not take TRUVADA if you are taking adefovir dipivoxil.

Do not take TRUVADA if you are taking tenofovir alafenamide.

Do not take TRUVADA 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 TRUVADA if the packaging is torn or shows signs of tampering.

If you are not sure whether you should be taking TRUVADA, talk to your doctor.

For people using TRUVADA to reduce the risk of getting HIV-1 infection:

TRUVADA can only help reduce your risk of getting HIV-1 before you are infected.

Do not take TRUVADA 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 TRUVADA to treat HIV. TRUVADA 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 TRUVADA 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 TRUVADA or at any time while taking TRUVADA. 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 breast feeding.

The safe use of TRUVADA in pregnancy has not been demonstrated. For this reason, it is important that women of child-

bearing age receiving treatment with TRUVADA use an effective method of contraception to avoid becoming pregnant.

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

The active substances in this medicine (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 TRUVADA. 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 (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 TRUVADA 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 TRUVADA.

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 TRUVADA 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 TRUVADA 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 (e.g. VOSEVI®)

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

How to take TRUVADA

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

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

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

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

How much to take

Take one TRUVADA tablet once daily or as advised by your doctor.

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

Your doctor will tell you how much TRUVADA 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 TRUVADA every day.

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

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

Do not stop taking TRUVADA without first talking to your doctor.

If you forget to take TRUVADA

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 TRUVADA, 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 TRUVADA tablet in a day.

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 131126), or in New Zealand the Poisons Centre (telephone 0800 764 766) or go to the accident and emergency department at your nearest hospital if you think you or anyone else may have taken too many TRUVADA tablets. Do this even if there are no signs of discomfort or poisoning. This may need urgent medical attention.

While you are taking TRUVADA

Things you must do

Tell your doctor or pharmacist that you are taking TRUVADA 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 TRUVADA to reduce your risk of getting HIV

Just taking TRUVADA may not keep you from getting HIV.

You must continue using safer sex practices while you are taking TRUVADA to reduce your risk of getting HIV.

You must stay HIV-negative to keep taking TRUVADA 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. TRUVADA 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 TRUVADA. Missing doses may increase your risk of getting HIV infection.

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

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

Things you must not do

Do not stop taking TRUVADA 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 TRUVADA to treat any other complaints unless your doctor says to

Things to be careful of

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

SIDE EFFECTS

Like all medicines, TRUVADA 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 TRUVADA, 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 TRUVADA to treat HIV-1 infection include:

- diarrhoea
- nausea
- tiredness
- headache
- dizziness
- depression
- problems sleeping

- abnormal dreams
- rash

Common side effects in people who take TRUVADA 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 TRUVADA 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 analog-containing medicines, like TRUVADA, for a long time.

Hepatic Flares

Your doctor should test you to see if you have chronic hepatitis B infection before you start taking TRUVADA.

If you have chronic hepatitis B infection you should not stop your TRUVADA 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 TRUVADA.

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

TRUVADA 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. TRUVADA 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 TRUVADA. 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 TRUVADA. 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 TRUVADA

Storage

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

Do not store TRUVADA or any other medicine in a bathroom or near a sink.

Do not leave TRUVADA in the car or on a window sill.

Heat and dampness can destroy some medicines.

Keep your TRUVADA tablets in the bottle with the cap tightly closed until you take them.

If you take TRUVADA tablets out of their pack they may not keep well.

Storage

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

PRODUCT DESCRIPTION

What the tablets look like

TRUVADA tablets are capsule-shaped and blue in colour.

The tablets, debossed on one side with the word “GILEAD” and on the other side with “701”.

TRUVADA tablets are supplied in bottles containing 30 tablets.

Ingredients

Each TRUVADA tablet contains the following active ingredients:

- 300 mg tenofovir disoproxil fumarate
- 200 mg emtricitabine

Each TRUVADA tablet also contains the following inactive ingredients:

- croscarmellose sodium

- lactose
- magnesium stearate (E572)
- microcrystalline cellulose
- pregelatinised maize starch

Film-coating:

- triacetin
- hypromellose (E464)
- indigo carmine aluminium lake (E132)
- lactose
- titanium dioxide (E171)

SPONSOR

TRUVADA tablets are supplied in

Australia by:

Gilead Sciences Pty Ltd
Level 6, 417 St Kilda Road
Melbourne, Victoria 3004

In New Zealand:

Gilead Sciences (NZ)
c/- Grant Thornton New Zealand
Limited,
L4, 152 Fanshawe Street

Auckland 1010

Date of preparation: 06 November 2020

AUST R 107072

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