

Consumer Medicine Information

TRUVADA[®] (tenofovir disoproxil fumarate/emtricitabine) 300 mg/200 mg TABLETS

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.

This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

WHAT TRUVADA TABLETS ARE USED FOR

- TRUVADA contains two active ingredients that belong to a group of antiviral medicines known as nucleoside and nucleotide reverse transcriptase inhibitor (NRTI). TRUVADA consists of two drugs (Viread[®] and Emtriva[®]) combined in one pill.
- TRUVADA is used to treat Human Immunodeficiency Virus (HIV) infection in adults. This medicine must be taken in combination with other anti-HIV medicines.
- This medicine is not a cure for HIV infection. While taking TRUVADA you may still develop infections or other illnesses associated with HIV infection.

BEFORE YOU TAKE TRUVADA TABLETS

When you must not take it

- If you are hypersensitive (allergic) to tenofovir, tenofovir disoproxil fumarate, emtricitabine or any of the other ingredients of TRUVADA. Read the side effects section to find out symptoms of allergy. The ingredients of TRUVADA are listed in the product description section of this leaflet.
- 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.
- Do not use TRUVADA to treat any other condition unless your doctor says that you should do so.

- 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.

Before you start to take TRUVADA

You must tell your doctor if:

- You are allergic to foods, dyes, preservatives or any other medicines.
- 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. It is not known whether the active substances (tenofovir and emtricitabine) in this medicine are excreted in human breast milk. 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.
- You have or have ever had liver problems including hepatitis B infection.
- You have or have ever had kidney problems.
- 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.

TRUVADA does not reduce the risk of passing HIV to others through sexual contact or blood contamination. Therefore, it is important to continue to take appropriate precautions to prevent passing HIV to others.

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

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.

- You are taking didanosine (also known as ddI or Videx).
- 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

The usual dose is one TRUVADA tablet once daily. TRUVADA is best taken with a meal or just afterwards, however taking it without food should not reduce the effectiveness of the medicine.

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

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

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.

How long to take TRUVADA

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

WHEN YOU ARE TAKING TRUVADA TABLETS

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.

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.

POSSIBLE SIDE EFFECTS

Like all medicines, TRUVADA can have side effects. 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.

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

- Nausea
- Diarrhoea
- Vomiting
- Flatulence
- Dizziness
- Fatigue/tiredness
- Headache
- Skin rash
- Difficulty breathing
- Muscle pain and weakness
- Changes in skin colour on the palms of the hands or soles of the feet
- Difficulty sleeping
- Abnormal dreams
- Pain

- Problems with digestion

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
- Nausea
- Stomach 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.

Hepatic Flares

If you have HIV infection and 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 blood tests for several months after stopping treatment.

Other side effects

This list of side effects is not complete. There have been other side effects in patients taking TRUVADA. Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

Redistribution, accumulation or loss of body fat may occur in people receiving combination antiretroviral therapy. Contact your doctor if you notice changes in body fat.

Some patients treated with VIREAD 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.

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

Storing TRUVADA

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 30°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.

Disposal

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 TRUVADA 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.

TRUVADA Tablet Ingredients

Each TRUVADA tablet contains contains 300 mg of tenofovir disoproxil fumarate and 200 mg of emtricitabine.

Other ingredients are:

- tablet core – croscarmellose sodium, lactose, magnesium stearate (E572), microcrystalline cellulose (E460) and pregelatinised maize starch
- tablet coating – triacetin, hypromellose (E464), indigo carmine aluminium lake (E132), lactose, titanium dioxide (E171)

SPONSOR

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Date of preparation: 24 October 2005