



Consumer Medicine Information

VIREAD

**Tenofovir 300mg
FILM-COATED 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 VIREAD tablets. It does not contain all the available information.

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

Keep this leaflet with the tablets. 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 VIREAD TABLETS ARE USED FOR

- VIREAD belongs to a group of antiviral medicines, called nucleotide reverse transcriptase inhibitors.
- VIREAD 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 VIREAD you may still develop infections or other illnesses associated with HIV infection.

BEFORE YOU TAKE VIREAD TABLETS

When you must not take them

- If you are hypersensitive (allergic) to tenofovir, tenofovir disoproxil fumarate or any of the other ingredients of VIREAD tablets. Read the side effects section to find out symptoms of allergy.
- Do not take VIREAD tablets if you are under the age of 18 years or over the age of 65.
- Do not use VIREAD tablets to treat any other condition unless your doctor says that you should do so.
- Do not give VIREAD tablets to anyone else, even though their symptoms may be similar to yours.
- Do not take VIREAD tablets after the expiry or "use by" date (EXP) printed on the back of the pack. If you take it after the expiry date has passed, it may not work as well.
- Do not take VIREAD tablets if the packaging is torn or shows signs of tampering.

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

Before you start to take them

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 VIREAD in human pregnancy has not been demonstrated. For this reason, it is important that women of child-bearing age receiving treatment with VIREAD use an effective method of contraception to avoid becoming pregnant. It is not known whether the active substance in this medicine is excreted in human breast milk. Consequently, nursing mothers should stop breast-feeding during treatment with VIREAD. 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 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 VIREAD it is important you remain under the care of a hospital or doctor who specialises in the treatment of HIV infection.

VIREAD 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 start taking VIREAD tablets in combination with other anti-HIV medicines for the first time. 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 your VIREAD tablets 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 VIREAD in combination with a number of 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 (ddi, VIDEX).
- Some medicines may affect the way others work. Your doctor or pharmacist will be able to tell you what to do when taking VIREAD tablets with other medicines.

HOW TO TAKE VIREAD

The usual dose is one VIREAD 300 mg tablet once daily. VIREAD 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.

VIREAD is absorbed rapidly. Do not take another VIREAD 300 mg tablet if vomiting has occurred unless it occurs immediately after taking VIREAD.

How much to take

Take one VIREAD 300 mg tablet once daily.

- If you are not sure how much VIREAD you should take, check with your doctor or pharmacist. Do not change the amount of VIREAD you take unless told to do so by your doctor.
- Your doctor will tell you how many VIREAD tablets to take and how often to take them. You will also find this information on the label of your medicine container.

How long to take them

Because your medicine helps to control your condition, but does not cure it, you will need to take the tablets every day. Do not stop taking VIREAD without first talking to your doctor.

If you forget to take VIREAD

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 VIREAD take it as soon as you remember. Do not take a double dose to make up for a forgotten dose.

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 POISON or 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 VIREAD tablets. Do this even if there are no signs of discomfort or poisoning. This may need urgent medical attention.

WHEN YOU ARE TAKING VIREAD TABLETS

Things you must do

- Tell your doctor or pharmacist that you are taking VIREAD tablets 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 VIREAD tablets 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 VIREAD tablets 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 the VIREAD tablets affect you.

POSSIBLE SIDE EFFECTS

Like all medicines, VIREAD 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 VIREAD tablets, 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

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 VIREAD** 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 these side effects are very rare.

Pancreatitis

If you have any of the following symptoms after starting taking your medication **DO NOT TAKE ANY MORE VIREAD TABLETS OR OTHER ANTI-HIV MEDICINES** and 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.

Lactic Acidosis

If you are on a medication for HIV and become very sick with fast breathing, stop taking **VIREAD TABLETS AND ANY OTHER ANTI-HIV MEDICINES** and consult your doctor **IMMEDIATELY**. You may have a condition known as 'Lactic Acidosis' which sometimes occurs in patients taking anti-HIV medicines. The fast breathing is due to high acid levels in the blood. This can be life threatening.

Hepatic Flares

If you have HIV infection and chronic hepatitis B infection you should not stop your VIREAD 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 VIREAD. You may require blood tests for several months after stopping treatment.

Other side effects

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 people may get other side effects while taking VIREAD tablets. 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 VIREAD

Storing VIREAD

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

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

Do not leave them in the car or on a window sill - heat and dampness can destroy some medicines.

Keep your VIREAD tablets in the bottle with the cap tightly closed until you take them. If you take VIREAD tablets out of their pack they may not keep well.

Disposal

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

PRODUCT DESCRIPTION

What VIREAD tablets look like

VIREAD 300 mg film-coated tablets are almond-shaped and light blue in colour. The tablets are debossed (indented) on one side with "GILEAD" and "4331" and on the other side with "300". VIREAD 300 mg film-coated tablets are supplied in bottles containing 30 tablets.

Ingredients

Each VIREAD tablet contains contains 300 mg of tenofovir disoproxil fumarate.

Other ingredients are:

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

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