

PACKAGE LEAFLET
LEBANON

PACKAGE LEAFLET: INFORMATION FOR THE USER

Viread 245 mg film-coated tablets Tenofovir disoproxil

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Viread is and what it is used for
2. What you need to know before you take Viread
3. How to take Viread
4. Possible side effects
5. How to store Viread
6. Contents of the pack and other information

If Viread has been prescribed for your child, please note that all the information in this leaflet is addressed to your child (in this case please read “your child” instead of “you”).

1. What Viread is and what it is used for

Viread contains the active substance *tenofovir disoproxil*. This active substance is an *antiretroviral* or antiviral medicine which is used to treat HIV or HBV infection or both. Tenofovir is a *nucleotide reverse transcriptase inhibitor*, generally known as an NRTI and works by interfering with the normal working of enzymes (in HIV *reverse transcriptase*; in hepatitis B *DNA polymerase*) that are essential for the viruses to reproduce themselves. In HIV Viread should always be used combined with other medicines to treat HIV infection.

Viread 245 mg tablets are a treatment for HIV (Human Immunodeficiency Virus) infection. The tablets are suitable for:

- **adults**
- **adolescents aged 12 to less than 18 years who have already been treated** with other HIV medicines which are no longer fully effective due to development of resistance, or have caused side effects.

Viread 245 mg tablets are also a treatment for chronic hepatitis B, an infection with HBV (hepatitis B virus). The tablets are suitable for:

- **adults**
- **adolescents aged 12 to less than 18 years.**

You do not have to have HIV to be treated with Viread for HBV.

This medicine is not a cure for HIV infection. While taking Viread you may still develop infections or other illnesses associated with HIV infection. You can also pass on HIV or HBV to others, so it is important to take precautions to avoid infecting other people.

2. What you need to know before you take Viread

Do not take Viread

- **If you are allergic** to tenofovir, tenofovir disoproxil fumarate or any of the other ingredients of this medicine listed in section 6.

If this applies to you, **tell your doctor immediately and don't take Viread.**

Warnings and precautions

Talk to your doctor or pharmacist before taking Viread.

- **Take care not to infect other people.** Viread does not reduce the risk of passing on HIV or HBV to others through sexual contact or blood contamination. You must continue to take precautions to avoid this.
- **Talk to your doctor or pharmacist if you have had kidney disease or if tests have shown problems with your kidneys.** Viread should not be given to adolescents with existing kidney problems. Before starting treatment, your doctor may order blood tests to assess your kidney function. Viread may affect your kidneys during treatment. Your doctor may order blood tests during treatment to monitor how your kidneys work. If you are an adult, your doctor may advise you to take the tablets less often. Do not reduce the prescribed dose, unless your doctor has told you to do so.

Viread is not usually taken with other medicines that can damage your kidneys (see *Other medicines and Viread*). If this is unavoidable, your doctor will monitor your kidney function once a week.

- **Bone problems.** Some adult patients with HIV taking combination antiretroviral therapy may develop a bone disease called osteonecrosis (death of bone tissue caused by loss of blood supply to the bone). The length of combination antiretroviral therapy, corticosteroid use, alcohol consumption, severe immunosuppression, higher body mass index, among others, may be some of the many risk factors for developing this disease. Signs of osteonecrosis are joint stiffness, aches and pains (especially of the hip, knee and shoulder) and difficulty in movement. If you notice any of these symptoms tell your doctor.

Bone problems (sometimes resulting in fractures) may also occur due to damage to kidney tubule cells (see section 4, *Possible side effects*).

- **Talk to your doctor if you have a history of liver disease, including hepatitis.** Patients with liver disease including chronic hepatitis B or C, who are treated with antiretrovirals, have a higher risk of severe and potentially fatal liver complications. If you have hepatitis B infection, your doctor will carefully consider the best treatment for you. If you have a history of liver disease or chronic hepatitis B infection your doctor may conduct blood tests to monitor your liver function.
- **Look out for possible signs of lactic acidosis** (excess of lactic acid in your blood) once you start taking Viread. Possible signs of lactic acidosis are:
 - deep, rapid breathing,
 - drowsiness,
 - nausea, vomiting and stomach pain.

This rare but serious side effect can cause enlargement of the liver and has occasionally been fatal. Lactic acidosis occurs more often in women, particularly if they are very overweight. If

you have liver disease you may also be more at risk of getting this condition. While you are being treated with Viread, your doctor will monitor you closely for any signs that you may be developing lactic acidosis.

- In the treatment of HIV, combination antiretroviral therapies (including Viread) may raise blood sugar, increase blood fats (hyperlipaemia), cause changes to body fat, and resistance to insulin (see section 4, *Possible side effects*).

If you are diabetic, overweight or have high cholesterol, talk to your doctor.

- **Look out for infections.** If you have advanced HIV infection (AIDS) and have an infection, you may develop symptoms of infection and inflammation or worsening of the symptoms of an existing infection once treatment with Viread is started. These symptoms may indicate that your body's improved immune system is fighting infection. Look out for signs of inflammation or infection soon after you start taking Viread. If you notice signs of inflammation or infection, **tell your doctor at once.**

In addition to the opportunistic infections, autoimmune disorders (a condition that occurs when the immune system attacks healthy body tissue) may also occur after you start taking medicines for the treatment of your HIV infection. Autoimmune disorders may occur many months after the start of treatment. If you notice any symptoms of infection or other symptoms such as muscle weakness, weakness beginning in the hands and feet and moving up towards the trunk of the body, palpitations, tremor or hyperactivity, please inform your doctor immediately to seek necessary treatment.

- **Talk to your doctor or pharmacist if you are over 65.** Viread has not been studied in patients over 65 years of age. If you are older than this and are prescribed Viread, your doctor will monitor you carefully.

Children and adolescents

Viread 245 mg tablets are **suitable** for:

- **HIV-1 infected adolescents aged 12 to less than 18 years who weigh at least 35 kg and who have already been treated** with other HIV medicines which are no longer fully effective due to development of resistance, or have caused side effects
- **HBV infected adolescents aged 12 to less than 18 years who weigh at least 35 kg.**

Viread 245 mg tablets are **not** suitable for the following groups:

- **Not for HIV-1 infected children** under 12 years of age
- **Not for HBV infected children** under 12 years of age.

For dosage see section 3, *How to take Viread*.

Other medicines and Viread

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

- **Don't stop any anti-HIV medicines** prescribed by your doctor when you start Viread if you have both HBV and HIV.
- **Do not take Viread** if you are already taking other medicines containing tenofovir disoproxil fumarate. Do not take Viread together with medicines containing adefovir dipivoxil (a medicine used to treat chronic hepatitis B).

- **It is very important to tell your doctor if you are taking other medicines that may damage your kidneys.**

These include:

- aminoglycosides, pentamidine or vancomycin (for bacterial infection),
- amphotericin B (for fungal infection),
- foscarnet, ganciclovir, or cidofovir (for viral infection),
- interleukin-2 (to treat cancer),
- adefovir dipivoxil (for HBV),
- tacrolimus (for suppression of the immune system).
- **Other medicines containing didanosine (for HIV infection):** Taking Viread with other antiviral medicines that contain didanosine can raise the levels of didanosine in your blood and may reduce CD4 cell counts. Rarely, inflammation of the pancreas and lactic acidosis (excess lactic acid in the blood), which sometimes caused death, have been reported when medicines containing tenofovir disoproxil fumarate and didanosine were taken together. Your doctor will carefully consider whether to treat you with combinations of tenofovir and didanosine.

Viread with food and drink

Take Viread with food (for example, a meal or a snack).

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

- **You must not take Viread during pregnancy** unless specifically discussed with your doctor. Although there are limited clinical data on the use of Viread in pregnant women, it is not usually used unless absolutely necessary.
- **Try to avoid getting pregnant** during treatment with Viread. You must use an effective method of contraception to avoid becoming pregnant.
- **If you become pregnant**, or plan to become pregnant, ask your doctor about the potential benefits and risks of your antiretroviral therapy to you and your child.
- **If you have taken Viread** during your pregnancy, your doctor may request regular blood tests and other diagnostic tests to monitor the development of your child. In children whose mothers took medicines like Viread (NRTIs) during pregnancy, the benefit from the protection against the virus outweighed the risk of side effects.
- **Do not breast-feed during treatment with Viread.** This is because the active substance in this medicine passes into human breast milk.
- If you are a woman with HIV or HBV do not breast-feed, to avoid passing the virus to the baby in breast milk.

Driving and using machines

Viread can cause dizziness. If you feel dizzy while taking Viread, **do not drive or ride a bicycle** and do not use any tools or machines.

Viread contains lactose

Tell your doctor before taking Viread if you cannot tolerate lactose or if you have an intolerance to any other sugars.

3. How to take Viread

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is:

- **Adults:** 1 tablet each day with food (for example, a meal or a snack).
- **Adolescents aged 12 to less than 18 years who weigh at least 35 kg:** 1 tablet each day with food (for example, a meal or a snack).

If you have particular difficulty swallowing, you can use the tip of a spoon to crush the tablet. Then mix the powder with about 100 ml (half a glass) of water, orange juice or grape juice and drink immediately.

- **Always take the dose recommended by your doctor.** This is to make sure that your medicine is fully effective, and to reduce the risk of developing resistance to the treatment. Do not change the dose unless your doctor tells you to.
- **If you are an adult and have problems with your kidneys,** your doctor may advise you to take Viread less frequently.
- If you have HBV your doctor may offer you an HIV test to see if you have both HBV and HIV.

Refer to the patient information leaflets of the other antiretrovirals for guidance on how to take those medicines.

If you take more Viread than you should

If you accidentally take too many Viread tablets, you may be at increased risk of experiencing possible side effects with this medicine (see section 4, *Possible side effects*). Contact your doctor or nearest emergency department for advice. Keep the tablet bottle with you so that you can easily describe what you have taken.

If you forget to take Viread

It is important not to miss a dose of Viread. If you miss a dose, work out how long since you should have taken it.

- **If it is less than 12 hours** after it is usually taken, take it as soon as you can, and then take your next dose at its regular time.
- **If it is more than 12 hours** since you should have taken it, forget about the missed dose. Wait and take the next dose at the regular time. Do not take a double dose to make up for a forgotten tablet.

If you throw up less than 1 hour after taking Viread, take another tablet. You do not need to take another tablet if you were sick more than 1 hour after taking Viread.

If you stop taking Viread

Don't stop taking Viread without your doctor's advice. Stopping treatment with Viread may reduce the effectiveness of the treatment recommended by your doctor.

If you have hepatitis B or HIV and hepatitis B together (co-infection), it is very important not to stop your Viread treatment without talking to your doctor first. Some patients have had blood tests or symptoms indicating that their hepatitis has got worse after stopping Viread. You may require blood tests for several months after stopping treatment. In some patients with advanced liver disease or cirrhosis, stopping treatment is not recommended as this may lead to worsening of your hepatitis.

- Talk to your doctor before you stop taking Viread for any reason, particularly if you are experiencing any side effects or you have another illness.
- Tell your doctor immediately about new or unusual symptoms after you stop treatment, particularly symptoms you associate with hepatitis B infection.
- Contact your doctor before you restart taking Viread tablets.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Possible serious side effects: tell your doctor immediately

- **Lactic acidosis** (excess lactic acid in the blood) is a **rare** (can affect up to 1 in every 1,000 patients) but serious side effect that can be fatal. The following side effects may be signs of lactic acidosis:
 - deep, rapid breathing
 - drowsiness
 - feeling sick (nausea), being sick (vomiting) and stomach pain

If you think that you may have **lactic acidosis**, **contact your doctor immediately**.

Other possible serious side effects

The following side effect is **uncommon** (this can affect up to 1 in every 100 patients):

- **pain in the tummy** (abdomen) caused by inflammation of the pancreas

The following side effects are **rare** (these can affect up to 1 in every 1,000 patients):

- inflammation of the kidney, **passing a lot of urine and feeling thirsty**, damage to kidney tubule cells
- **changes to your urine** and **back pain** caused by kidney problems, including kidney failure
- softening of the bones (with **bone pain** and sometimes resulting in fractures), which may occur due to damage to kidney tubule cells

- **fatty liver**
- **Changes in body shape**
In the treatment of HIV, combination antiretroviral therapy (including Viread) may change your body shape, by changing the way body fat is distributed. You may lose fat from your legs, arms and face; gain fat around the tummy (abdomen) and internal organs; get larger breasts or fatty lumps on the back of the neck ('buffalo hump'). The cause and the long-term effects of these changes are not yet known.

If you think that you may have any of these serious side effects, talk to your doctor.

Most frequent side effects

The following side effects are **very common** (these can affect at least 10 in every 100 patients):

- diarrhoea, being sick (vomiting), feeling sick (nausea), dizziness, rash, feeling weak

Tests may also show:

- decreases in phosphate in the blood

Other possible side effects

The following side effects are **common** (these can affect up to 10 in every 100 patients):

- headache, stomach pain, feeling tired, feeling bloated, flatulence

Tests may also show:

- liver problems

The following side effects are **uncommon** (these can affect up to 1 in every 100 patients):

- breakdown of muscle, muscle pain or weakness

Tests may also show:

- decreases in potassium in the blood
- increased creatinine in your blood
- pancreas problems

The breakdown of muscle, softening of the bones (with bone pain and sometimes resulting in fractures), muscle pain, muscle weakness and decreases in potassium or phosphate in the blood may occur due to damage to kidney tubule cells.

The following side effects are **rare** (these can affect up to 1 in every 1,000 patients):

- pain in the tummy (abdomen) caused by inflammation of the liver
- swelling of the face, lips, tongue or throat

In the treatment of HIV, combination antiretroviral therapy may also cause increased fats in the blood (hyperlipaemia) and resistance to insulin. Your doctor will test for these changes.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store Viread

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the bottle and carton after {EXP}. The expiry date refers to the last day of that month.

Store below 30°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Viread contains

- **The active substance is** tenofovir. Each Viread tablet contains 245 mg of tenofovir disoproxil (as fumarate).
- **The other ingredients are** microcrystalline cellulose (E460), starch pregelatinised, croscarmellose sodium, lactose monohydrate, and magnesium stearate (E572) which make up the tablet core, and lactose monohydrate, hypromellose (E464), titanium dioxide (E171), glycerol triacetate (E1518) and indigo carmine aluminium lake (E132) which make up the tablet coating. Refer to section 2 “Viread contains lactose”.

What Viread looks like and contents of the pack

Viread 245 mg film-coated tablets are light blue, almond-shaped, film-coated tablets, of dimensions 16.8 mm x 10.3 mm, debossed on one side with “GILEAD” and “4331” and on the other side with “300”. Viread 245 mg film-coated tablets are supplied in bottles containing 30 tablets. Each bottle contains a silica gel desiccant that must be kept in the bottle to help protect your tablets. The silica gel desiccant is contained in a separate sachet or canister and should not be swallowed.

The following pack size is available: outer cartons containing 1 bottle of 30 film-coated tablets.

Marketing Authorisation Holder and Manufacturer

Gilead Sciences International Ltd
Cambridge
CB21 6GT
United Kingdom

Manufacturer:
Gilead Sciences Limited
IDA Business & Technology Park
Carrigtohill
County Cork
Ireland

To report any side effect(s):

Please contact the relevant competent authority.

This is a Medicament

- Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of each of children.

Council of Arab Health Ministers and Union of Arab Pharmacists

EUJUL13LBSEP13