

PRODUCT INFORMATION LEAFLET

TENOFOVIR DISOPROXIL FUMARATE TABLETS 300 mg

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, health care provider or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet please tell your doctor, health care provider or pharmacist.

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1. What Tenofovir Disoproxil Fumarate 300mg Tablets is and what it is used for
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1. WHAT TENOFOVIR DISOPROXIL FUMARATE 300MG TABLETS IS AND WHAT IT IS USED FOR

Tenofovir Disoproxil Fumarate 300mg Tablets is a treatment for Human Immunodeficiency Virus (HIV) infection in adults over 18 years old and/or for chronic hepatitis B, an infection with hepatitis B virus (HBV) in adults.

You do not have to have HIV to be treated with Tenofovir Disoproxil Fumarate 300mg Tablets for HBV.

Tenofovir Disoproxil Fumarate 300mg Tablets contains the active substance *tenofovir disoproxil fumarate*. Tenofovir prevents the multiplication of HIV and HBV in the body and is used for the treatment of HIV infection or chronic hepatitis B, or both. Specifically, tenofovir interferes with enzymes used for making copies of the virus—in HIV tenofovir interferes with virus *reverse transcriptase* and in HBV it interferes with virus *DNA polymerase*. Because of its actions, tenofovir is known as *nucleotide reverse transcriptase inhibitor* (often abbreviated NRTI).

Antiviral medicines used for HIV infection are known as *antiretrovirals*. To prevent the virus become resistant, tenofovir should always be given in combination with other antiretrovirals when treating HIV.

This medicine is not a cure for HIV infection. While taking Tenofovir Disoproxil Fumarate 300mg

Tablets 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. BEFORE YOU TAKE TENOFOVIR DISOPROXIL FUMARATE 300MG TABLETS

Do not take Tenofovir Disoproxil Fumarate 300mg Tablets

If you are allergic (hypersensitive) to tenofovir disoproxil fumarate or to any of the other ingredients of Tenofovir Disoproxil Fumarate 300mg Tablets listed at the end of this leaflet.

If this applies to you, tell your doctor immediately and don't take Tenofovir Disoproxil Fumarate 300mg Tablets.

Take special care with Tenofovir Disoproxil Fumarate 300mg Tablets

Tell your doctor if you have had kidney disease or if tests have shown problems with your kidneys. Tenofovir Disoproxil Fumarate 300mg Tablets may affect your kidneys. Before starting this medicine you may need blood tests to check how well your kidneys are working.

The tests can help to decide how you should take your medicine. Blood tests may also be required during treatment to check the health of your kidneys. Tenofovir Disoproxil Fumarate 300mg Tablets is not usually taken with other medicines that can damage your kidneys (see *Taking other medicines*). If this is unavoidable, you may need regular tests to check how well your kidneys are working.

Talk to your doctor if you are over 65. Tenofovir Disoproxil Fumarate 300mg has not been studied in patients over 65 years of age. If you are older than this and are prescribed Tenofovir Disoproxil Fumarate 300mg Tablets, your doctor will monitor you carefully.

Do not give Tenofovir Disoproxil Fumarate 300mg Tablets to children and adolescents under 18 years of age.

Talk to your doctor or health care provider if you have a history of liver disease, including hepatitis. HIV-infected 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 are infected with HIV and hepatitis B virus, 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 Tenofovir Disoproxil Fumarate 300mg Tablets. 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 and in patients that 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 Tenofovir Disoproxil Fumarate 300mg Tablets, your doctor will monitor you closely for any signs that you may be developing lactic acidosis. If you think you may have lactic acidosis, contact your doctor immediately.

Take care not to infect other people. Tenofovir Disoproxil Fumarate 300mg Tablets does not eliminate 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. In the treatment of HIV, combination antiretroviral therapies 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 a so-called opportunistic infection, you may develop symptoms of infection and inflammation or worsening of the symptoms of this infection once treatment with Tenofovir Disoproxil Fumarate 300mg Tablets 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 Tenofovir Disoproxil Fumarate 300mg Tablets. If you notice signs of inflammation or infection, tell your doctor or health care provider at once.

Bone problems. Some 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 duration of antiretroviral therapy, use of a corticosteroid such as dexamethasone or prednisolone, alcohol consumption, severe immunosuppression, and being overweight 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, tell your doctor.

Bone problems (sometimes resulting in fractures) may also occur due to damage to the kidney cells.

Taking other medicines

Tell your doctor, pharmacist or health care provider if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Don't stop any anti-HIV medicines prescribed by your doctor when you start lenovovir Disoproxil Fumarate 300mg if you have both HBV and HIV. Do not take Tenofovir Disoproxil Fumarate 300mg Tablets if you are already taking other medicines containing tenofovir disoproxil fumarate. Do not take Tenofovir Disoproxil Fumarate 300mg Tablets and adefovir dipivoxil at the same time. It is very important to tell your doctor or health care provider if you are taking other medicines that may damage your kidneys.

These include:

- aminoglycosides (such as gentamicin or tobramycin) or vancomycin (for bacterial infection)
- amphotericin B or pentamidine (for fungal infection)
- foscarnet, ganciclovir and cidofovir (for viral infection)
- tacrolimus (for suppression of the immune system)
- interleukin-2 (to treat cancer)

- adefovir dipivoxil (for HBV)

Other medicines containing didanosine (for HIV infection): Taking Tenofovir Disoproxil Fumarate 300mg Tablets with medicines that contain didanosine can raise the levels of didanosine in your blood. 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. Combining tenofovir with didanosine can also reduce the effects of antiretroviral therapy. Your doctor will carefully consider whether to treat you with a combination of tenofovir and didanosine.

Taking Tenofovir Disoproxil Fumarate 300mg Tablets with food and drink

Take Tenofovir Disoproxil Fumarate 300mg Tablets with a meal.

Pregnancy and breast-feeding

Pregnant or breast-feeding mothers should not take Tenofovir Disoproxil Fumarate 300mg Tablets unless specifically directed by the doctor. Be sure to tell your doctor immediately if you are or may be pregnant.

If you are interested in breastfeeding your baby, you should discuss the risks and benefits with your doctor or healthcare provider.

Important information about some of the ingredients of Tenofovir Disoproxil Fumarate 300mg Tablets

If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicinal product.

Driving and using machines

Tenofovir Disoproxil Fumarate 300mg Tablets can cause dizziness. If you feel dizzy while taking Tenofovir Disoproxil Fumarate 300mg Tablets, do not drive and do not use hazardous tools or machines.

3. HOW TO TAKE TENOFOVIR DISOPROXIL FUMARATE 300MG TABLETS

Always take Tenofovir Disoproxil Fumarate 300mg Tablets exactly as your doctor or health care provider has told you. This is to make sure that your medicine is fully effective, and to reduce the risk of developing resistance to the treatment. You should check with your doctor, pharmacist or health care provider if you are not sure. Always take the dose recommended by your doctor or health care provider. Do not change the dose unless your doctor tells you to.

The usual dose for adults is one tablet each day. Tenofovir Disoproxil Fumarate 300mg Tablets should be taken on with a meal. Swallow Tenofovir Disoproxil Fumarate 300mg Tablets whole with water or another liquid. If you cannot swallow the tablet, 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.

Children:

This product is not for use by children and adolescents (under 18 years of age).

If you have problems with your kidneys, your doctor or health care provider may advise you to take Tenofovir Disoproxil Fumarate 300mg Tablets less frequently.

Don't stop any anti-HIV medicines prescribed by your doctor when you start Tenofovir Disoproxil Fumarate 300mg if you have both HBV and HIV.

If you have HBV your doctor may offer you an HIV test to see if you have both HBV and HIV.

If you take more Tenofovir Disoproxil Fumarate 300mg Tablets than you should:

If you accidentally take too many Tenofovir Disoproxil Fumarate 300mg Tablets, contact your doctor or nearest emergency department for advice. Take the tablet container with you so that you can easily describe what you have taken.

If you forget to take Tenofovir Disoproxil Fumarate 300mg Tablets:

It is important not to miss a dose of Tenofovir Disoproxil Fumarate 300mg Tablets. If you miss a dose of Tenofovir Disoproxil Fumarate 300mg Tablets, take it as soon as you can, and then take your next dose at its regular time. However, if your next dose is due within 6 hours, 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 vomit less than 1 hour after taking Tenofovir Disoproxil Fumarate 300mg Tablets, take another tablet. You do not need to take another tablet if you were sick more than 1 hour after taking Tenofovir Disoproxil Fumarate 300mg Tablets.

If you stop taking Tenofovir Disoproxil Fumarate 300mg Tablets:

Don't stop taking Tenofovir Disoproxil Fumarate 300mg Tablets without your doctor's or health care provider's advice. Stopping treatment with Tenofovir Disoproxil Fumarate 300mg Tablets may reduce the effectiveness of the treatment. Talk to your doctor or health care provider before you stop taking Tenofovir Disoproxil Fumarate 300mg Tablets for any reason, particularly if you are experiencing any side effects or you have another illness. Contact your doctor or health care provider before you restart taking Tenofovir Disoproxil Fumarate 300mg Tablets.

If you have hepatitis B or HIV and hepatitis B together (co-infection), it is very important not to stop your Tenofovir Disoproxil Fumarate 300mg Tablets treatment without talking to your doctor or health care provider first. Some patients have had blood tests or symptoms indicating that their hepatitis has got worse after stopping Tenofovir Disoproxil Fumarate 300mg Tablets. 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. Tell your doctor or health care provider immediately about new or unusual symptoms after you stop treatment, particularly symptoms you associate with hepatitis B infection. If you have any further questions on the use of this product, ask your doctor, health care provider or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Tenofovir Disoproxil Fumarate 300mg Tablets can cause side effects, although not everybody gets them.

Very common side effects

(These can affect at least 10 in every 100 patients)

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

Tests may also show:

- abnormally low phosphate in the blood

Common side effects

(These can affect up to 10 in every 100 patients)

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

Tests may also show: liver problems

Rare side effects

(These can affect up to 1 in every 1,000 patients)

- excess lactic acid in the blood (lactic acidosis, a 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
- pain in the abdomen caused by inflammation of the pancreas
- changes to your mine and back pain caused by kidney problems, including kidney failure
- rash

Tests may also show:

- decrease in potassium in the blood
- increased creatinine in your blood
- liver and pancreas problems

Very rare side effects

(These can affect less than 1 in every 10,000 patients)

- shortness of breath

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

- feeling weak

Tests may also show

- damage to kidney tubule cells

Side effects with unknown frequency:

You may experience injury to the kidney, passing a lot of urine and feeling thirsty, as well as muscle pain or weakness and softening of the bones (with bone pain and sometimes resulting in fractures).

The following side effects have been reported in HIV infected patients treated with medicines of the group of NRTIs, to which Tenofovir Disoproxil Fumarate 300mg Tablets belongs:

- changes in body shape due to changes in fat distribution. These may include loss of fat from legs, arms and face, increased fat in the abdomen and internal organs, breast enlargement and fatty lumps on the back of the neck ('buffalo hump').
- increases in blood fats (hyperlipaemia) and an abnormal increase in blood sugar. Your doctor will test for these changes.
- appearance of infection as part of 'immune reactivation syndrome' (see "Take special care with { Tenofovir Disoproxil Fumarate 300mg Tablets"}).

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 health care provider.

5. HOW TO STORE TENOFOVIR IMSOPROXIL FUMARATE 300MG TABLETS

Store below 30°C, protected from moisture.

Keep out of the reach and sight of children.

Do not use Tenofovir Disoproxil Fumarate 300mg Tablets 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.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required.

6. FURTHER INFORMATION

What Tenofovir Disoproxil Fumarate 300mg Tablets contains

The active ingredient is tenofovir disoproxil fumarate 300 mg (equivalent to tenofovir disoproxil **245 mg**)

The other ingredients are:

Core tablet: croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose and pregelatinised starch.

Film coat: lactose monohydrate, hypromellose, titanium dioxide and triacetin.

What Tenofovir Disoproxil Fumarate 300mg Tablets looks like and contents of the pack

White to off-white, capsule shaped, film-coated tablets, debossed with “RE42” on one side and plain on other, packaged in white, opaque 60 cc HDPE bottle with white opaque polypropylene fine-ribbed 33 mm screw cap with induction seal liner or with child resistant closures with wad having induction seal liner. Pack size: 30 tablets.

The tablets should not be divided.

Supplier and manufacturer

Manufactured by:

Strides Shasun Ltd

Bangalore- India