

## PATIENT INFORMATION LEAFLET

### SCHEDULING STATUS

S4

### **PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM**

**ZEFIN 300 mg TABLETS** (Tablet)

Tenofovir disoproxil fumarate

**Read all of this leaflet carefully before you start taking ZEFIN 300 mg TABLETS.**

Keep this leaflet. You may need to read it again.

If you have further questions, please ask your doctor or your pharmacist.

- **ZEFIN 300 mg TABLETS** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

### **1. WHAT ZEFIN 300 mg TABLETS CONTAIN**

The active substance is tenofovir disoproxil fumarate.

Each film-coated tablet contains 300 mg of tenofovir disoproxil fumarate. Contains lactose.

The other ingredients are: croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose and pregelatinized starch.

The coating ingredients contain: hypromellose, lactose monohydrate, titanium dioxide (C.I. No: 77891), and triacetin.

### **2. WHAT ZEFIN 300 mg TABLETS ARE USED FOR**

**ZEFIN 300 mg TABLETS** is a treatment for Human Immunodeficiency Virus (HIV) infection in adults.

**ZEFIN 300 mg TABLETS** is always used in combination with other anti-HIV medicines to treat patients with HIV-1 infection.

### **3. BEFORE YOU TAKE ZEFIN 300 mg TABLETS**

**Do not take ZEFIN 300 mg TABLETS:**

If you are hypersensitive (allergic) to tenofovir disoproxil fumarate, or any of the other ingredients of **ZEFIN 300 mg TABLETS**.

If you have kidney failure.

If you are pregnant or breastfeeding.

**Take special care with ZEFIN 300 mg TABLETS:**

**ZEFIN 300 mg TABLETS may lead to serious problems with your liver or cause too much acid in your blood. If left untreated, this may cause death. The safety and efficacy of ZEFIN 300 mg TABLETS in patients who are infected with both human immunodeficiency virus (HIV) and hepatitis B virus (HBV) have not been established. ZEFIN 300 mg TABLETS should not be used for treatment of chronic HBV infection. You should be closely monitored by your doctor for several months if you are infected with HBV and discontinue the use of ZEFIN 300 mg TABLETS.**

**ZEFIN 300 mg TABLETS** may cause lactic acidosis, together with an enlarged liver, which can be fatal. Deep, rapid breathing, drowsiness, and non-specific symptoms such as nausea, vomiting and stomach pain, might indicate the development of lactic acidosis. Lactic acidosis occurs more often in women. Patients who are very overweight are more at risk. If you became pregnant while taking **ZEFIN 300 mg TABLETS** your baby may develop blood and nervous system disorders. Your doctor will monitor your baby's condition. Pancreatitis is a dangerous inflammation of the pancreas that may cause death. Tell your doctor right away if you develop stomach pain, nausea or vomiting. These can be signs of pancreatitis.

**ZEFIN 300 mg TABLETS** may change your body shape, by changing the way body fat is distributed. You may lose fat from your legs, arms and face and/or gain fat around the abdomen (tummy) 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 are taking **ZEFIN 300 mg TABLETS** for the first time you may develop a condition known as Immune Reconstitution Inflammatory Syndrome (IRIS), within the first few months

of treatment. This condition can cause opportunistic infections that are being treated to become worse or opportunistic diseases that were asymptomatic to be unmasked. Tell your doctor or healthcare professional if your general health worsens or if you think you may have an infection. You should not stop taking **ZEFIN 300 mg TABLETS**. Your doctor will treat the infections appropriately.

Tell your doctor if you have liver disease (including hepatitis B). **ZEFIN 300 mg TABLETS** should not be used to treat chronic hepatitis B virus infection (HBV; an ongoing liver infection). Tell your doctor if you have or think you may have HBV.

Tell your doctor if you have had kidney disease, or if tests have shown problems with your kidneys. **ZEFIN 300 mg TABLETS** may affect your kidneys.

**ZEFIN 300 mg TABLETS** is not usually taken with other medicines that can damage your kidneys. If this is unavoidable, your doctor will monitor your kidney function.

Inform your doctor or healthcare professional if you have any pre-existing liver disease including Hepatitis B or C.

**ZEFIN 300 mg TABLETS** can have serious medicine interactions. Tell your doctor or healthcare professional about all other medicine you are taking (see "Taking other medicines with **ZEFIN 300 mg TABLETS**").

You may develop a condition known as osteonecrosis while taking **ZEFIN 300 mg TABLETS**. Seek medical advice if you experience joint aches and pain, joint stiffness or difficulty in movement.

Bone problems: Some patients taking combination antiretroviral therapy, including **ZEFIN 300 mg TABLETS** may develop a bone disease.

You may continue to develop opportunistic infections and other complications of HIV infection while taking **ZEFIN 300 mg TABLETS**. You should remain under close observation by healthcare professionals experienced in the treatment of patients with associated HIV disease. Regular monitoring of viral load and CD4 counts needs to be done.

You are still at risk of transmitting HIV to others through sexual contact or blood contamination while taking current antiretroviral therapy including **ZEFIN 300 mg TABLETS**. Appropriate precautions should continue to be employed.

The safety and effectiveness of **ZEFIN 300 mg TABLETS** in children and patients younger than 18 years has not been determined.

If you have advanced HIV infection (AIDS) and have any infection, you may develop acute symptoms of the infection or inflammation and a worsening of the symptoms of an existing infection once treatment with **ZEFIN 300 mg TABLETS** is started. If you notice signs of inflammation or infection, or deterioration thereof, tell your doctor at once.

**Taking ZEFIN 300 mg TABLETS with food and drink:**

**ZEFIN 300 mg TABLETS** can be taken with or without food.

**Pregnancy and Breastfeeding:**

You must not take **ZEFIN 300 mg TABLETS** during pregnancy.

Do not breastfeed during treatment with **ZEFIN 300 mg TABLETS**. It is not known whether the active substance in **ZEFIN 300 mg TABLETS** passes into human breast milk.

If you are pregnant or breastfeeding your baby please consult your doctor, pharmacist or other healthcare professional for advice before taking **ZEFIN 300 mg TABLETS**

**Important information about some of the ingredients of ZEFIN 300 mg TABLETS**

**ZEFIN 300 mg TABLETS** contains lactose (a type of sugar), if you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking **ZEFIN 300 mg TABLETS**.

**Taking other medicines with ZEFIN 300 mg TABLETS:**

Always tell your healthcare professional if you are taking any other medicine.

(This includes complementary or traditional medicines.)

Tell your doctor if you are taking abacavir, emtricitabine, indinavir or lamivudine (for HIV infection).

Tell your doctor if you are taking atazanavir and/or lopinavir/ritonavir (for HIV infection): If you are taking any of these medicines, your doctor may need to monitor your therapy more closely or you may not be able to use **ZEFIN 300 mg TABLETS**.

If you are taking **ZEFIN 300 mg TABLETS** and atazanavir together, you should also be taking ritonavir.

Tell your doctor if you are taking other medicines containing didanosine (for HIV infection). Taking **ZEFIN 300 mg TABLETS** with other antiviral medicines that contain didanosine can raise the levels of didanosine in your blood. Inflammation of the pancreas, and neuropathy (disorders with the nerves) can occur. Your doctor will carefully consider whether to treat you with combinations of tenofovir and didanosine.

Tell your doctor if you are taking other medicines that may reduce your kidney function. Some examples include, adefovir dipivoxil, cidofovir, acyclovir, valacyclovir, ganciclovir and valganciclovir.

#### **4. HOW TO TAKE ZEFIN 300 mg TABLETS**

Do not share medicines prescribed for you with any other person.

Always take **ZEFIN 300 mg TABLETS** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. If you have the impression that the effect of **ZEFIN 300 mg TABLETS** is too strong or too weak, talk to your doctor or pharmacist.

Your doctor will tell you how long your treatment with **ZEFIN 300 mg TABLETS** will last.

Stay under a healthcare provider's care when taking **ZEFIN 300 mg TABLETS**. Do not change your treatment or stop treatment without first talking with your healthcare provider.

Always take **ZEFIN 300 mg TABLETS** in combination with other anti-HIV medicines.

The usual dose of **ZEFIN 300 mg TABLETS** is one tablet once a day, taken with or without food.

Tell your doctor if you have kidney problems.

#### **If you take more ZEFIN 300 mg TABLETS than you should:**

Seek emergency medical attention if you think you have used too much of **ZEFIN 300 mg TABLETS**.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

**If you forget to take ZEFIN 300 mg TABLETS:**

If you forget to take a dose, take it as soon as you remember, and then continue as before. Do not take a double dose to make up for forgotten individual doses.

**5. POSSIBLE SIDE EFFECTS**

**ZEFIN 300 mg TABLETS** can have side effects.

If any of the following happens, stop taking **ZEFIN 300 mg TABLETS** and tell your doctor immediately or go to the casualty department at your nearest hospital:

Hives; difficulty breathing; swelling of your face, lips, tongue, or throat.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **ZEFIN 300 mg TABLETS**. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

Lactic acidosis (severe increase of lactic acid in the blood, 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.

Liver damage – nausea; stomach pain; low fever; loss of appetite; dark urine; clay-coloured stools; jaundice (yellowing of the skin or eyes).

Fever, chills, sore throat, cough, or other signs of infection.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following side effects and they worry you or if any of these symptoms are severe or do not go away:

Headache; lack of energy; dizziness; sleep problems (inability to sleep); depression; problems with nerves; numbness, tingling, pins and needles; nausea (feeling sick); being sick (vomiting); diarrhoea; pain in the abdomen (tummy); heartburn; skin rashes, muscle pain; flatulence (excess amount of air/gas in stomach); lack of appetite; inflammation of the pancreas; inflammation of the liver;

shortness of breath; pain; back pain; chest pain; kidney problems, fever; sweating; weight loss; changes in body fat, including an increased amount of fat in the upper back and neck, breast and around the trunk, loss of fat from the legs, arms and face may also happen.

Not all side effects reported for **ZEFIN 300 mg TABLETS** are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while taking **ZEFIN 300 mg TABLETS** please consult your doctor, pharmacist or other healthcare professional for advice.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

## **6. STORING AND DISPOSING OF ZEFIN 300 mg TABLETS**

Store at or below 30 °C (room temperature). Keep containers tightly closed.

Do not use if seal over bottle opening is broken or missing.

Store all medicines out of reach of children.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

## **7. PRESENTATION OF ZEFIN 300 mg TABLETS**

### **HDPE Container Pack:**

Tablets are packed in white opaque HDPE containers and white opaque closures with induction sealing wad with one no. of 1 g silica gel sachet and polyester fibre coil. Each container contains 30 tablets.

Pack size: 30's - One HDPE container contains 30 tablets.

## **8. IDENTIFICATION OF ZEFIN 300 mg TABLETS**

White to off-white, oval shaped, biconvex, film-coated tablets debossed with 'I' on one side and '36' on the other side.

## **9. REGISTRATION NUMBER/REFERENCE NUMBER**

44/20.2.8/0307

**10. NAME AND ADDRESS OF REGISTRATION HOLDER**

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**11. DATE OF PUBLICATION**

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