

## PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

**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.

### **In this leaflet:**

1. What Lamivudine/Tenofovir Disoproxil Fumarate 300mg/300mg Tablets is and what it is used for
2. Before you take Lamivudine/Tenofovir Disoproxil Fumarate 300mg/300mg Tablets
3. How to take Lamivudine/Tenofovir Disoproxil Fumarate 300mg/300mg Tablets
4. Possible side effects
5. How to store Lamivudine/Tenofovir Disoproxil Fumarate 300mg/300mg Tablets
6. Further information

### **1. WHAT LAMIVUDINE/TENOFOVIR DISOPROXIL FUMARATE 300mg/300mg TABLETS IS AND WHAT IT IS USED FOR**

Lamivudine/Tenofovir Disoproxil Fumarate 300mg/300mg Tablets is a treatment for Human Immunodeficiency Virus (HIV) infection in adults over 18 years of age.

Lamivudine/Tenofovir Disoproxil Fumarate 300mg/300mg Tablets contains the active substances *lamivudine* and *tenofovir disoproxil fumarate*. Both of these are *antiviral* medicines. Lamivudine is a *nucleoside reverse transcriptase inhibitor*. Tenofovir is a *nucleotide reverse transcriptase inhibitor*. Both active substances interfere with enzymes used by HIV for making copies of itself and, by doing so, block the reproduction of the virus.

Antiviral medicines used for HIV infection are known as *antiretrovirals*. To prevent the virus from becoming resistant, Lamivudine/Tenofovir Disoproxil Fumarate 300mg/300mg Tablets should always be given in combination with other antiretrovirals when treating HIV.

**This medicine is not a cure for HIV infection.** While taking Lamivudine/Tenofovir Disoproxil

**PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER**

Fumarate 300mg/300mg Tablets you may still develop infections or other illnesses associated with HIV infection.

**2. BEFORE YOU TAKE LAMIVUDINE/ TENOFOVIR DISOPROXIL FUMARATE 300mg/300mg TABLETS**

**Do not take Lamivudine/ Tenofovir Disoproxil Fumarate 300mg/300mg Tablets:**

If you are allergic (hypersensitive) to lamivudine, tenofovir disoproxil fumarate or any of the other ingredients of Lamivudine/Tenofovir Disoproxil Fumarate 300mg/300mg Tablets listed at the end of this leaflet. If this applies to you, tell your doctor immediately and don't take Lamivudine/ Tenofovir Disoproxil Fumarate 300mg/300mg Tablets.

**Take special care with Lamivudine/Tenofovir Disoproxil Fumarate 300mg/300mg Tablets:**

Tell your doctor if you have had kidney disease or if tests have shown problems with your kidneys. If so, the dose of tenofovir and lamivudine may need to be reduced. In such cases other formulations of tenofovir and lamivudine than Lamivudine/ Tenofovir Disoproxil Fumarate 300mg/300mg Tablets should be used.

Lamivudine/Tenofovir Disoproxil Fumarate 300mg/300mg Tablets may affect your kidneys. Before starting this medicine you may need blood tests to check how well your kidneys are working. Blood tests may also be required during treatment to check the health of your kidneys. Lamivudine/ Tenofovir Disoproxil Fumarate 300mg/300mg Tablets is not usually taken with other medicines that can damage your kidneys. If this is unavoidable, you may need regular tests to check how well your kidneys are working.

Lamivudine/ Tenofovir Disoproxil Fumarate 300mg/300mg Tablets should not be used by children or 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

## **PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER**

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 Lamivudine/ Tenofovir Disoproxil Fumarate 300mg/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 Lamivudine/ Tenofovir Disoproxil Fumarate 300mg/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. Lamivudine/ Tenofovir Disoproxil Fumarate 300mg/300mg Tablets does not eliminate the risk of passing on HIV to others through sexual contact or contamination with blood. You must continue to take precautions to avoid this.

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 Lamivudine/ Tenofovir Disoproxil Fumarate 300mg/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 Lamivudine/ Tenofovir Disoproxil Fumarate 300mg/300mg Tablets. If you notice signs of inflammation or infection, tell your doctor or health care provider at once.

Some patients 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,

## **PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER**

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.

Do not take Lamivudine/ Tenofovir Disoproxil Fumarate 300mg/300mg Tablets if you are already taking other medicines containing tenofovir disoproxil fumarate, emtricitabine, lamivudine or zalcitabine. Do not take Lamivudine/ Tenofovir Disoproxil Fumarate 300mg/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 or vancomycin (for bacterial infection)
- amphotericin B or pentamidine (for fungal infection)
- foscarnet, ganciclovir, or cidofovir (for viral infection)
- adefovir dipivoxil (for hepatitis B virus infection)
- tacrolimus (for suppression of the immune system)

Other medicines containing didanosine (for HIV infection): Taking Lamivudine/Tenofovir Disoproxil Fumarate 300mg/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, has 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 Lamivudine/ Tenofovir Disoproxil Fumarate 300mg/300mg Tablets with food and drink**

## **PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER**

Take Lamivudine/ Tenofovir Disoproxil Fumarate 300mg/300mg Tablets with a meal.

### **Pregnancy and breast-feeding**

Pregnant or breast-feeding mothers should not take Lamivudine/ Tenofovir Disoproxil Fumarate 300mg/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 Lamivudine/ Tenofovir Disoproxil Fumarate 300mg/300mg Tablets**

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

### **Driving and using machines**

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

## **3. HOW TO TAKE LAMIVUDINE/ TENOFOVIR DISOPROXIL FUMARATE 300mg/300mg TABLETS**

Always take {Lamivudine/ Tenofovir Disoproxil Fumarate 300mg/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. Lamivudine/ Tenofovir Disoproxil Fumarate 300mg/300mg Tablets should be taken on with a meal. Swallow Lamivudine/ Tenofovir Disoproxil Fumarate 300mg/300mg Tablets whole with water or another liquid.

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

## **PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER**

If your doctor decides to stop one of the components of Lamivudine/ Tenofovir Disoproxil Fumarate 300mg/300mg Tablets or change the dose of Lamivudine/ Tenofovir Disoproxil Fumarate 300mg/300mg Tablets, you may be given lamivudine and/or tenofovir separately instead of the combined medicine or other medicines for the treatment of HIV infection.

Your doctor will prescribe Lamivudine/ Tenofovir Disoproxil Fumarate 300mg/300mg Tablets with other antiretroviral medicines. Please refer to the patient information leaflets of the other antiretrovirals for guidance on how to take those medicines.

### **If you take more Lamivudine/ Tenofovir Disoproxil Fumarate 300mg/300mg Tablets than you should:**

If you accidentally take too many Lamivudine/ Tenofovir Disoproxil Fumarate 300mg/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 Lamivudine/ Tenofovir Disoproxil Fumarate 300mg/300mg Tablets:**

It is important not to miss a dose of Lamivudine/ Tenofovir Disoproxil Fumarate 300mg/300mg Tablets. If you miss a dose of Lamivudine/ Tenofovir Disoproxil Fumarate 300mg/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 Lamivudine/ Tenofovir Disoproxil Fumarate 300mg/300mg Tablets, take another tablet. You do not need to take another tablet if you were sick more than 1 hour after taking Lamivudine/ Tenofovir Disoproxil Fumarate 300mg/300mg Tablets.

### **If you stop taking Lamivudine/ Tenofovir Disoproxil Fumarate 300mg/300mg Tablets:**

Don't stop taking Lamivudine/Tenofovir Disoproxil Fumarate 300mg/300mg Tablets without your doctor's or health care provider's advice. Stopping treatment with Lamivudine/ Tenofovir Disoproxil Fumarate 300mg/300mg Tablets may reduce the effectiveness of the treatment. Talk to your doctor or health care provider before you stop taking Lamivudine/ Tenofovir Disoproxil

## **PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER**

Fumarate 300mg/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 Lamivudine/Tenofovir Disoproxil Fumarate 300mg/300mg Tablets.

If you have hepatitis B or HIV and hepatitis B together (co-infection), it is very important not to stop your Lamivudine/ Tenofovir Disoproxil Fumarate 300mg/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 Lamivudine/Tenofovir Disoproxil Fumarate 300mg/300mg Tablets. You may require blood tests for several months after stopping treatment. 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, Lamivudine/ Tenofovir Disoproxil Fumarate 300mg/300mg Tablets can cause side effects, although not everybody gets them.

**Tell your doctor about any of the following side effects:**

#### **Very common side effects**

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

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

*Tests may also show:*

- abnormally low levels of phosphate in the blood

#### **Common side effects**

(These can affect at least 1 in every 100 patients treated, but less than 1 in every 10 patients treated)

- stomach pain, flatulence
- Headache

## **PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER**

- difficulties sleeping
- rash (including red spots or blotches sometimes with blistering and swelling of the skin, which may be an allergic reaction), itching, changes in skin colour including darkening of the skin in patches
- Hair loss
- feeling weak, fever
- Pain in muscles and joints

### **Uncommon side effects**

(These can affect at least 1 in every 1,000 patients treated, but less than 1 in every 100 patients treated)

- anaemia (low red blood cell count, which can make you tired and out of breath), low white blood cell count (which could make you more prone to infection), low platelet count (which could make you more prone to bleeding).

*Tests may also show*

- increased blood levels of liver function tests

### **Rare side effects**

(These can affect at least 1 in every 10,000 patients treated, but less than 1 in every 1,000 patients treated)

- 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
- Inflammation of the liver (hepatitis)
- kidney problems, including kidney failure. Symptoms may include nausea and fatigue, but also passing a lot of urine and feeling thirsty. This may also lead to softening of the bones (with bone pain and sometimes resulting in fractures).

*Tests may also show*



## **PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER**

- increased creatinine in your blood

### **Very rare side effects**

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

- shortness of breath
- nerve injury causing weakness and sensations of tingling, pricking, or numbness of the skin, especially in the feet and hands (peripheral neuropathy)

*Tests may also show:*

- damage to kidney tubule cells

### **Side effects with unknown frequency:**

Muscle pain, breakdown of muscle tissue, disorders of bone

The following side effects have been reported in HIV infected patients treated with medicines of the group of NRTIs, to which Lamivudine/ Tenofovir Disoproxil Fumarate 300mg/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 symptoms of infection as part of the 'immune reactivation syndrome'.

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 {LAMIVUDINE/TENOFOVIR DISOPROXIL FUMARATE 300mg/300mg TABLETS}**

Keep out of the reach and sight of children.

Do not use (Lamivudine/Tenofovir Disoproxil Fumarate 300mg/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.

## **PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER**

Store at a temperature not exceeding 30 °C in the original package, protected from Light.

As with all medicines, keep this product out of the reach of children.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

### **6. FURTHER INFORMATION**

#### **What Lamivudine/Tenofovir Disoproxil Fumarate 300mg/300mg Tablets contains**

The active ingredients are Lamivudine 300 mg and Tenofovir Disoproxil Fumarate 300 mg (equivalent to Tenofovir Disoproxil 245 mg).

The other ingredients are: Microcrystalline cellulose, Croscarmellose sodium, Magnesium Stearate. Colour contains, Lactose monohydrate, Hypromellose, Titanium Dioxide, Triacetin

#### **What Lamivudine/Tenofovir Disoproxil Fumarate 300mg/300mg Tablets looks like and contents of the pack**

White to off-white coloured, capsule shaped, biconvex, film coated tablets debossed 'CL71' on one side of the tablet and having plain surface on other surface.

30 Tablets packed in 75cc white, round HDPE container with pack insert finally induction sealed.

10 Tablets are packed in Alu/Cold forming blister pack, such 10 blisters in a carton.

Following minimum batch details is coded on Container Label

Batch No., Mfg. Date and Exp. Date.

#### **Supplier**

Macleods Pharmaceuticals Ltd.

304, Atlanta Arcade,

Marol Church Road,

Andheri (East)

Mumbai- 400 059,

India

Phone: +91-22-66762800

Fax: +91-22-2821 6599

E-mail: [exports@macleodspharma.com](mailto:exports@macleodspharma.com)

#### **Manufacturer**

Macleods Pharmaceuticals Ltd

Unit II, Plot No. 25 - 27,

Sr. No. 366,

Premier Ind. Estate,

Kachigam, Daman (U,T),

India

Tel: +91-0260 2244337

Fax: +91-0260 2241565