PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

TYRICTEN 200/300mg TABLETS (Tablet)

Read all of this leaflet carefully before you start taking TYRICTEN 200/300mg TABLETS

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **TYRICTEN 200/300mg 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 TYRICTEN 200/300mg TABLETS CONTAIN

The active substances are emtricitabine and tenofovir disoproxil fumarate.

Each film-coated tablet contains 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate (which is equivalent to 245 mg tenofovir disoproxil).

The tablets contain 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 TYRICTEN 200/300mg TABLETS ARE USED FOR

TYRICTEN 200/300mg TABLETS contains two active substances, emtricitabine and tenofovir disoproxil, that are used to treat human immunodeficiency virus (HIV-1) infection in adults.

Each of these active substances, also known as antiretroviral medicines, work by interfering with an enzyme (reverse transcriptase) that is essential for the virus to multiply.

TREATMENT WITH TYRICTEN 200/300mg TABLETS DOES NOT PREVENT TRANSMISSION OF HIV.

3. BEFORE YOU TAKE TYRICTEN 200/300mg TABLETS

Do not take TYRICTEN 200/300mg TABLETS:

- If you are hypersensitive (allergic) to emtricitabine, tenofovir disoproxil fumarate, or any of the other ingredients of **TYRICTEN 200/300mg TABLETS**.
- If you have moderate to severe kidney disease.
- If you are pregnant or breast-feeding.

Take special care with TYRICTEN 200/300mg TABLETS:

TYRICTEN 200/300mg TABLETS may lead to serious problems with your liver or cause to much acid in your blood. If left untreated, this may cause death. The safety and efficacy of TYRICTEN 200/300mg TABLETS in patients who are infected with both human immunodeficiency virus (HIV) and hepatitis B virus (HBV) have not been established. TYRICTEN 200/300mg 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 TYRICTEN 200/300mg TABLETS.

- **TYRICTEN 200/300mg 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, particularly if they are overweight.
- Tell your doctor if you have liver disease (including hepatitis B). **TYRICTEN 200/300mg TABLETS** should not be used to treat hepatitis B virus infection (HBV; an on-going liver infection). Tell your doctor if you have or think you may have HBV. Your doctor may test you to see if you have HBV before you begin your treatment with **TYRICTEN 200/300mg TABLETS**. If you have HBV and you take **TYRICTEN 200/300mg TABLETS**, your condition may suddenly

worsen when you stop taking **TYRICTEN 200/300mg TABLETS.** Your doctor will examine you and order laboratory tests regularly for several months after you stop taking **TYRICTEN 200/300mg TABLETS** to see if your HBV has worsened.

- Tell your doctor if you have had kidney disease, or if tests have shown problems with your kidneys. **TYRICTEN 200/300mg TABLETS** may affect your kidneys. Before starting treatment, your doctor may order blood tests to assess kidney function. Your doctor may also order blood tests during treatment to monitor your kidneys.
- **TYRICTEN 200/300mg TABLETS** is not usually taken with other medicines that can damage your kidneys. If this is unavoidable, your doctor will monitor your kidney function.
- Bone problems: Some patients taking combination antiretroviral therapy may develop a bone disease. Your doctor may consider monitoring your bones if you have a history of bone fracture or are at risk for osteopenia (a condition where bone mineral density is lower than normal).
- **TYRICTEN 200/300mg TABLETS** 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 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.
- **TYRICTEN 200/300mg TABLETS** has not been studied in patients over 65 years of age. If you are older than this and prescribed **TYRICTEN 200/300mg TABLETS**, your doctor will monitor you carefully.
- The safety and effectiveness of **TYRICTEN 200/300mg TABLETS** in children and adolescents has not been determined.
- Look out for infections. If you have advanced HIV infection (AIDS) and have an infection, you may develop symptoms of infection or inflammation or worsening of the symptoms of an existing infection once treatment with **TYRICTEN 200/300mg TABLETS** is started. If you notice signs of inflammation or infection, tell your doctor at once.
- **TYRICTEN 200/300mg TABLETS** contains lactose and is unsuitable for individuals with the hereditary disorders of galactosaemia or glucose / galactose malabsorption syndrome.

Taking TYRICTEN 200/300mg TABLETS with food and drink:

TYRICTEN 200/300mg TABLETS can be taken with or without food.

Pregnancy and Breast-feeding:

- You must not take **TYRICTEN 200/300mg TABLETS** during pregnancy.
- Do not breast-feed during treatment with **TYRICTEN 200/300mg TABLETS**. It is not known whether the active substances in this medicine pass into human breast milk.
- If you are a woman with HIV it is recommended that you do not breast-feed, to avoid passing the virus to the baby in breast milk.

- If you are pregnant or breast-feeding your baby while taking **TYRICTEN 200/300mg TABLETS**, please consult your doctor, pharmacist or other health care professional for advice.

Driving and using machinery:

TYRICTEN 200/300mg TABLETS may cause dizziness. Do not drive or use any tools or machines if you feel dizzy.

Taking other medicines with TYRICTEN 200/300mg TABLETS:

- You should not take **TYRICTEN 200/300mg TABLETS** if you are already taking other medicines that contain emtricitabine, tenofovir disoproxil or lamivudine.
- Tell your doctor if you are taking, or have recently taken any other medicines.
- Tell your doctor if you are taking atazanavir and/or lopinavir/ritonavir: 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 **TYRICTEN 200/300mg TABLETS**.
- Tell your doctor if you are taking other medicines containing didanosine (for HIV infection). Taking **TYRICTEN 200/300mg 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.

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **TYRICTEN 200/300mg TABLETS** with these medicines may cause undesirable interactions. Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines).

4. HOW TO TAKE TYRICTEN 200/300mg TABLETS

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

Always take **TYRICTEN 200/300mg 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 **TYRICTEN 200/300mg TABLETS** is too strong or too weak, talk to your doctor or pharmacist.

- The usual adult dose is one tablet once a day, taken with or without food.

If you take more TYRICTEN 200/300mg TABLETS than you should:

- Seek emergency medical attention if you think you have used too much of this medicine.

In the event of overdose, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison centre.

If you forget to take TYRICTEN 200/300mg 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

TYRICTEN 200/300mg TABLETS can have side-effects.

Get emergency medical help immediately if you have any of **these signs of an allergic reaction:**

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

Call your doctor at once if you have any of these serious side-effects:

- 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.

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 (strange dreams, 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; rashes (including red spots or blotches sometimes with blistering and swelling of the skin), which may be allergic reactions, itching, changes in skin colour including darkening of the skin in patches; joint pain; muscle pain; runny nose; flatulence (excess amount of air/gas in stomach); lack of appetite; pancreas problems; anxiety, chest pain; pneumonia; shortness of breath; back pain; blood in the urine; fever; sweating; weight loss.

PLEASE CONSULT YOUR DOCTOR OR HEALTHCARE PROFESSIONAL TO PERFORM AND/OR HAVE REGULAR MEDICAL EXAMINATIONS WHILST ON TYRICTEN 200/300mg TABLETS.

Not all side-effects reported for this medicine are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

6. STORING AND DISPOSING OF TYRICTEN 200/300mg TABLETS

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

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

KEEP ALL THE MEDICINES OUT OF REACH AND SIGHT OF CHILDERN

Return all unused medicine to your pharmacist.

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

7. PRESENTATION OF TYRICTEN 200/300mg TABLETS

HDPE Container Pack:

Tablets are packed in white opaque HDPE containers with a 38 mm – 40 CR closure with induction sealing wad, containing 1 No. of silica gel sachet.

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

8. IDENTIFICATION OF TYRICTEN 200/300mg TABLETS

White to off-white, modified capsule shaped, film-coated tablets, debossed with 'I' on one side and '37' on other side.

9. REGISTRATION NUMBER/REFERENCE NUMBER

44/20.2.8/0086

10. NAME AND ADDRESS OF REGISTRATION HOLDER

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11. DATE OF PUBLICATION

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