PATIENT INFORMATION LEAFLET FOR

TAVIRANT

SCHEDULING STATUS:

S4

TAVIRANT 200/25/25 mg, film-coated tablets

Emtricitabine, rilpivirine hydrochloride and tenofovir alafenamide fumarate

Contains sugar: 411,055 mg anhydrous lactose and 129,450 mg lactose monohydrate.

Read all of this leaflet carefully before you start taking TAVIRANT

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet (see section 4).
- TAVIRANT 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.

What is in this leaflet:

1. What TAVIRANT is and what it is used for

TAVIRANT is indicated in combination with other antiretroviral medicines for the treatment of adults infected with human immunodeficiency virus type 1 (HIV-1).

2. What you need to know before you take TAVIRANT

Do not take TAVIRANT:

- if you are hypersensitive (allergic) to emtricitabine, rilpivirine, tenofovir alafenamide or any of the other ingredients of TAVIRANT (listed in section 6)
- in combination with carbamazepine, oxcarbazepine, phenobarbital, phenytoin, dexamethasone (except as a single dose treatment) rifabutin, rifampicin, rifapentine, St. John's Wort, proton-pump inhibitors (PPIs) such as lansoprazole, dexlansoprazole, omeprazole, rabeprazole, pantoprazole and esomeprazole as co-administration may result in loss of therapeutic effect of TAVIRANT.

Warnings and precautions

Special care should be taken with TAVIRANT:

- if you have pain in joints (osteonecrosis)
- if you have diabetes or have galactose intolerance
- if you have hepatitis B or C
- if you have been diagnosed with a liver disease
- if you have been diagnosed with a kidney disease or have abnormal kidney function
- if you have any HIV-1 mutations

- if you are taking other HIV medication

Tell your doctor or health care provider if you develop any of the following symptoms when taking TAVIRANT:

- If you develop changes in body fat as such changes have been seen in some patients taking TAVIRANT. These changes may include increased amount of fat in the upper back and neck (“buffalo hump”), breast, and around the main part of your body (trunk). Loss of fat from the legs, arms and face may also happen.
- Clinical worsening of a known condition or the appearance of a new condition after initiating antiretroviral therapy (immune reconstitution syndrome).
- TAVIRANT does not reduce the risk of passing HIV to others through sexual contact or blood contamination. Therefore, it is important to continue to take appropriate precautions to prevent passing HIV to others. Even if you are receiving treatment for HIV, you are still at risk of contracting other infections and other complications of the HIV infection. Therefore, you should remain under close observation by your doctor.
- An increase in weight or blood lipid tests.
- Your baby has abnormal blood tests or is behaving abnormally.
- Abnormal liver blood tests or symptoms associated with a condition called lactic acidosis such as nausea, vomiting, stomach pain, weight loss and feeling tired.
- If you have existing or develop any infections. Regular monitoring of your CD4 count is required.

Children and adolescents

The safety of TAVIRANT in children younger than the age of 18 is not known. TAVIRANT is therefore not recommended for patients younger than 18 years of age.

Other medicines and TAVIRANT

Always tell your health care provider if you are taking any other medicines. (This includes all complementary or traditional medicines).

The following medicines or substances may increase or decrease blood levels and increase the risk of adverse events associated with TAVIRANT, please inform your doctor if you are taking any of the following medicines before you start treatment with TAVIRANT:

- atazanavir and cobicistat
- tenofovir alafenamide
- atazanavir and ritonavir
- darunavir and ritonavir
- lopinavir and ritonavir
- tipranavir and ritonavir
- dolutegravir
- rilpivirine
- efavirenz
- maraviroc, nevirapine, raltegravir
- oxcarbazepine, phenytoin, phenobarbital
- carbamazepine
- sertraline
- St. John’s wort
- ciclosporin
- norgestimate
- midazolam
- didanosine

- delavirdine, efavirenz, etravirine, nevirapine
- lopinavir, ritonavir, fosamprenavir, saquinavir, tipranavir, indinavir, nelfinavir
- antacids containing magnesium, aluminium or calcium
- ketoconazole, fluconazole, itraconazole, isavuconazole, posaconazole, voriconazole
- rifabutin, rifampicin, rifapentine
- ledipasvir, sofosbuvir, velpatasvir, voxilaprevir
- clarithromycin, erythromycin, troleandomycin
- dexamethasone
- omeprazole, lansoprazole, rabeprazole, pantoprazole, esomeprazole
- famotidine, cimetidine, nizatidine, ranitidine
- paracetamol.

Current antiretroviral therapy does not cure HIV and has not been proven to prevent the transmission of HIV to others through blood, other bodily secretion or sexual contact. Appropriate precautions to prevent transmission of HIV should continue to be employed.

TAVIRANT may reduce the effect of the following medicine:

- methadone.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking TAVIRANT.

Pregnancy

The use of TAVIRANT is not recommended during pregnancy.

Breastfeeding

Mothers should not breastfeed their infants when taking TAVIRANT.

Fertility

There are no data on fertility from the use of TAVIRANT in humans.

Driving and using machines

TAVIRANT may affect the ability to drive and use machines. Dizziness and drowsiness may occur.

It is not always possible to predict to what extent TAVIRANT may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which TAVIRANT affects them.

TAVIRANT contains lactose

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

3. How to take TAVIRANT

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

Always take TAVIRANT exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

The usual dose of TAVIRANT is one tablet once a day with meals.

Your doctor will tell you how long your treatment with TAVIRANT will last.

Do not stop treatment early. If you have the impression that the effect of TAVIRANT is too strong or too weak, tell your doctor or pharmacist.

If you take more TAVIRANT than you should

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

If you forget to take TAVIRANT

Do not take a double dose to make up for the forgotten individual doses.

4. Possible side effects

TAVIRANT can have side effects.

Not all side effects reported for TAVIRANT are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking TAVIRANT, please consult your health care provider for advice.

If any of the following happens, stop taking TAVIRANT and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all serious side effects. If you have them, you may have had a serious reaction to TAVIRANT.

You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- headache, dizziness, abnormal dreams
- nausea, diarrhoea, vomiting, passing of gas, upper stomach pain
- feeling tired
- abnormal blood results of the liver and pancreas
- depression
- difficulty falling asleep.

Less frequent side effects:

- worsening of a known condition or the appearance of a new condition after initiating TAVIRANT
- inflammation of the liver
- abnormal blood tests
- decreased appetite
- sleep disorders, depressed mood
- symptoms such as feeling weak, tired, pale or yellowish skin, cold hands and feet (anaemia)
- feeling of indigestion
- joint pain.

Side effects with unknown frequency:

- increased creatinine blood levels

- change in total cholesterol, LDL- cholesterol, HDL - cholesterol and triglycerides associated with redistribution of body fat
- change in weight and blood sugar levels.

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

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8 or to Cipla Medpro (Pty) Ltd. by e-mail: drugsafetysa@cipla.com or telephone: 080 222 6662 (toll free). By reporting side effects, you can help provide more information on the safety of TAVIRANT.

5. How to store TAVIRANT

Store at or below 30 °C.

Store all medicines out of reach of children.

Store in the original container.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

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

6. Contents of the pack and other information

What TAVIRANT contains

The active substances are emtricitabine 200 mg, rilpivirine hydrochloride equivalent to 25 mg rilpivirine and tenofovir alafenamide fumarate equivalent to 25 mg tenofovir alafenamide.
The other ingredients are anhydrous lactose, crospovidone, ferric oxide red, lactose monohydrate, magnesium stearate, opadry AMB pink 80W54485 (iron oxide red, iron oxide yellow, lecithin (soya), polyvinyl alcohol part hydrolyzed, talc, titanium dioxide and xanthan gum), povidone, polysorbate and sodium starch glycolate.

What TAVIRANT looks like and contents of the pack

Pink coloured, capsule shaped biconvex film-coated tablets plain on both sides.

TAVIRANT is packed in a 60 cc white round HDPE bottle consisting of a silica gel bag 3 gm Stripax (Multisorb) R/F. The bottle consists of a 33 mm white child resistant cap. The HDPE bottles may be packed with or without a printed cardboard carton. Pack sizes are 28 and 30 tablets.

Holder of Certificate of Registration

CIPLA MEDPRO (PTY) LTD.

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