APPROVED PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

VIRLAM

Lamivudine and tenofovir disoproxil fumarate 300 mg/300 mg

VIRLAM contains sugar (lactose, 39,4 mg)

Read all of this leaflet carefully before you start taking VIRLAM

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- VIRLAM 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

6. Contents of the pack and other information

1. What VIRLAM is and what it is used for

VIRLAM contains Lamivudine 300 mg and tenofovir disoproxil fumarate 300 mg, one of a group of medicines called reverse transcriptase inhibitors.

VIRLAM is used

- to treat Human Immunodeficiency Virus (HIV) infection in adults over 18 years of age.

2. What you need to know before you take VIRLAM

Do not take VIRLAM:

- if you are allergic (hypersensitive) to lamivudine or tenofovir, or any of the other ingredients in VIRLAM
- if you have moderate to severe impairment of kidney function
- if you are pregnant or breastfeeding
- if you are younger than 18 years of age
- if you Are taking zalcitabine (see " Other medicines and VIRLAM ")

Warnings and precautions

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VIRLAM may cause serious liver damage or too much acid in your blood. This may result in death if left untreated. Report to our doctor immediately if you develop nausea, vomiting, stomach pain, loss of appetite, generally feel unwell or develop rapid or shallow breathing. This condition may develop after a few or several months of treatment. You should be closely monitored by your doctor for several months if you are infected with HBV and stop taking VIRLAM.

Tell your doctor or healthcare professional before taking VIRLAM:

Take special care / Special care should be taken with VIRLAM if:

- you have symptoms such as deep, rapid breathing, drowsiness, and non-specific symptoms, such as nausea, vomiting and stomach pain. This is a serious, life-threatening side-effect known as lactic acidosis (excess of lactic acid in your blood). Lactic acidosis occurs more often in women, particularly if they 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 VIRLAM, please report any of these symptoms to your doctor as a matter of urgency.
- you have hepatitis B virus (HBV) infection (see initial boxed "WARNING")

- you have a kidney disorder (see "Possible side effects"). Please report to your doctor immediately if you develop swelling of the lower limbs, hands, body or face, are short of breath and if you pass very little or no urine. You may have to go for regular blood tests to monitor your kidney function
- you develop excess fat on your abdomen (stomach), behind your neck, or your breasts may enlarge, while your legs and arms become thinner. Contact your doctor as soon as possible if you notice changes in body fat distribution. You may require blood tests to monitor your cholesterol and blood sugar (glucose) levels.
- you develop severe stomach pain or cramps accompanied by fever, chills, and severe nausea and vomiting.
- you are taking VIRLAM you may still develop infections or other illnesses associated with HIV infection as VIRLAM is not a cure for HIV infection.
- VIRLAM does not reduce the risk of passing HIV to others through sexual contact or contamination with blood. Therefore, it is important to continue to take appropriate precautions to prevent passing HIV to others.
- you develop signs and symptoms of inflammation from previous infections soon after treatment with VIRLAM is started. It is believed that these symptoms are due to an

improvement in the body's immune response, causing inflammation in response to infections that may have been present with no obvious symptoms. If you notice any symptoms of infection, please inform your doctor immediately.

- you develop a decrease in bone mineral density of the hip and spine (your hip and spine may become brittle). However, this is not associated with an increased risk of fracture. Your doctor will monitor you for this and may decide to prescribe a calcium and vitamin D supplement for you.
- report to your doctor as soon as possible if you experience stiffness, aches and pains (especially of the hip, knee and shoulder) and difficulty in movement. These symptoms may be due to a bone disease called osteonecrosis (loss of blood supply to the bone).

Children and adolescents:

Do not give VIRLAM to children and adolescents younger than 18 years of age.

Other medicines and VIRLAM

Always tell your healthcare provider if you are taking any other medicine (this includes complementary or traditional medicines).

- Do not take VIRLAM with any other medicines containing lamivudine, tenofovir

disoproxil fumarate, abacavir, emtricitabine adefovir dipivoxil.

- It is not recommended to take didanosine, or zalcitabine (see “Do not take VIRLAM” in combination with VIRLAM.
- Atazanavir, atazanavir/ritonavir combination, lopinavir/ritonavir combination darunavir/ritonavir combination (medicines used to treat HIV infection) taken in combination with VIRLAM can increase the effect of VIRLAM and can lead to kidney problems.
- Taking sofosbuvir and VIRLAM together can increase the effect of VIRLAM and lower the effect of Sofosbuvir.
- Taking VIRLAM in combination with ledipasvir/sofosbuvir combination may increase the effect of VIRLAM and side effect may occur.
- Taking co-trimoxazole (antibiotic used to treat infection) may increase the effect of VIRLAM and should be avoided if high doses of co-trimoxazole is prescribed for treatment of lung infection and infection from a parasite called *Toxoplasma gondii.*

- Do not take VIRLAM if you recently used or are using medicine which can influence the kidneys i.e. aminoglycosides (antibiotics), amphotericin B (used to treat fungal infections), foscarnet (used to treat virus infections), ganciclovir (used to treat the viral infection - cytomegalovirus), pentamidine (used to treat lung infection), vancomycin (antibiotic), cidofovir (used to treat viral infections) or interleukin-2 (used to treat cancer).
- Tacrolimus (used to suppress the immune system) can influence the kidneys and should be used with care when taken in combination with VIRLAM

VIRLAM with food and drink:

VIRLAM should be taken with food.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before using VIRLAM. You should not use VIRLAM if you are pregnant. Mothers on VIRLAM should not breastfeed their babies.

Driving and using machines:

It is not always possible to predict to what extent VIRLAM 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 VIRLAM affects them.

- VIRLAM may cause dizziness. If you feel dizzy while taking VIRLAM, do not drive and do not use any tools or machines.

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

3. How to take VIRLAM

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

Always take VIRLAM exactly as your doctor has instructed you.

You should check with your doctor or pharmacist if you are unsure.

Adults:

The usual dose is one VIRLAM tablet once daily with food.

Your doctor will tell you how long your treatment with VIRLAM will last. Do not stop taking VIRLAM without discussing it with your doctor. If you have the impression that the effect of VIRLAM is too strong or too weak, please discuss this with your doctor.

If you take more VIRLAM than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre. Always take VIRLAM exactly as your doctor has instructed you.

If you forget to take VIRLAM:

If you forget to take VIRLAM, take a dose as soon as you remember, then continue to take VIRLAM at the usual times. Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

VIRLAM can have side effects.

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

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

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

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to VIRLAM. 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:

- shortness of breath (dyspnoea).

This is a serious side effect. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Blood test indicating raised liver enzyme levels
- Hives, itching, sweating
- Muscle pain
- Lack of energy, back or chest pain, pain
- Blood tests indicating abnormal levels for the following cholesterol or triglycerides, amylase (indication of pancreas infections), creatine kinase (indication of muscle damage), white blood cell count, glucose
- Blood in urine, glucose in urine as detected with urine analyses.

Less frequent side effects:

- Low white- (symptoms include repeated fevers and infections) and red blood cell counts (symptoms include fatigue, dizziness, weakness and light-headedness, pale skin), low platelet count (symptoms include easy and excessive bruising, prolonged bleeding from cuts), abnormal organ or tissue development and function
- Exhaustion, muscle cramps body weakness due to a condition called lactic acidosis
- Inflammation of the pancreas (symptoms include upper abdominal pain, fever, nausea, vomiting)
- Inflammation of the liver (symptoms include discoloured urine and stools, diarrhoea, abdominal swelling, distention or bloating, loss of appetite)
- Kidney problems, kidney failure (swelling of your legs, ankles, and feet from retention of fluids, confusion, reduced amount of urine), nausea, drowsiness or fatigue)
- Tingling or prickling
- Breakdown of muscle fibers (symptoms include muscle weakness, fatigue, dark coloured urine)
- Fatty liver disease as diagnosed by your doctor. Symptoms include fatigue, weight loss, abdominal pain, yellow skin and eyes.
- Muscle weakness, softening of the bones (bone pain and fractures easy)
- Pain in the pelvis, pain of a burning sensation while urinating, swelling especially in the face, leg or feet. It may be symptoms of kidney inflammation or kidney disorders
- Proteins in the urine as detected with urine tests

- A low level of the electrolyte potassium in the blood as detected with blood tests. Symptoms can include weakness and fatigue, heart palpitations, muscle cramps.

The following side effects have been reported but the frequency for them to occur is not known:

- A condition called immune reconstitution syndrome (where the immune system starts to recover but then responds to a previous infection). Symptoms include fever and worsening of breathing issues.

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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of VIRLAM.

5. How to store VIRLAM

Store all medicines out of reach of children.

Store at or below 30 °C in original container.

Keep container tightly closed.

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

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 VIRLAM contains

The active substance is lamivudine and tenofovir disoproxil fumarate.

Each capsule contains lamivudine 300 mg and 245 mg of tenofovir disoproxil, equivalent to 300 mg tenofovir disoproxil fumarate.

The other ingredients are:

Corn starch

Croscarmellose sodium

Lactose monohydrate

Magnesium Stearate

Microcrystalline cellulose

Polysorbate 80

What VIRLAM looks like and contents of the pack

VIRLAM is a capsule-shaped, bilayered, biconvex, film-coated tablets with one layer orange and the other layer white in colour, "LT" debossed on one side with central break

line and plain on the other side

VIRLAM is packed into a white, cylindrical HDPE bottle closed with a white opaque HDPE non child resistance cap with a white opaque liner. containing 28 or 30 tablets.

Each bottle contains 28 or 30 tablets

Holder of Certificate of Registration

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