PATIENT INFORMATION LEAFLET

FOR LOMIDA

SCHEDULING STATUS: S4

LOMIDA (50/300 mg, film-coated tablets).

Dolutegravir sodium equivalent to dolutegravir 50 mg and lamivudine 300 mg

Contains sugar: mannitol 145,00 mg

Read all of this leaflet carefully before you start taking LOMIDA

- Keep this leaflet. You may need to read it again.
- If you have any further questions, 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**)
- LOMIDA 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 LOMIDA is and what it is used for

LOMIDA is a combination antiretroviral medicine, and it is indicated for the treatment of HIV type 1 infection in adults aged 18 years and older.

2. What you need to know before you take LOMIDA

Do not take LOMIDA:

- if you are hypersensitive (allergic) to dolutegravir, lamivudine, or any of the other ingredients of LOMIDA (listed in **section 6**)
- if you have been diagnosed with severe liver disease
- if you have been diagnosed with severe kidney disease
- if you are taking any of the following medicines as LOMIDA may impact their concentrations and cause serious effects:
    - Dofetilide
    - Pilsicainide.

Warnings and precautions

Take special care with LOMIDA:

- if you experience symptoms such as shortness of breath, feeling tired, nausea (the urge to vomit), pain in the stomach, and weight loss. Your doctor may need to do certain tests to determine your lactate levels.
- if you develop allergic reactions such as a rash, organ failure, including liver damage
- if you develop a high temperature, swelling, sometimes of the face or mouth, pain in muscle or joints, infection in the eye, blisters, inflammation in the liver, as treatment with LOMIDA may be stopped. Delay in stopping treatment with LOMIDA at the beginning of allergic reactions may result in a life-threatening reaction.

- if you develop changes in body fat, as such changes have been seen in some patients taking LOMIDA and other anti-HIV medicines. 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.
- if you have been diagnosed with liver disease, including hepatitis B or C
- if you have been diagnosed with chronic kidney disease. Your doctor will constantly monitor your kidney function throughout the duration of your treatment with LOMIDA.
- if you experience symptoms like nausea, vomiting, and/or pain in the stomach as they may have to do laboratory tests to exclude pancreatitis (inflammation of the pancreas)
- if you experience symptoms which are associated with anaemia (such as dizziness, pale skin, and shortness of breath), neutropenia (such as fever, mouth ulcers or susceptibility to infections), or if you experience a tingling (pins and needles) sensation in the hands and feet, muscle tension, convulsions (fits) and abnormal behaviour
- if you experience joint aches and pain, joint stiffness or difficulty in movement, as your health care provider may need to do tests to check your bone mineral density or may prescribe medicines to help your bone mineral density
- if you show any symptoms of infection while you are taking LOMIDA. People with advanced HIV infection (AIDS) have weak immune systems and are more likely to develop serious infections (opportunistic infections). When these people start with the treatment, they may find that old hidden infections (such as tuberculosis) flare up, causing signs and symptoms of inflammation (such as localised swelling, area appears red and hot, painful). These symptoms are probably caused by the body’s immune system becoming stronger, so that the body starts to fight these infections.

- if you have abnormal metabolic processes, such as, increased cholesterol, glucose or lactate in the blood, or are resistant to insulin. Your health care provider may perform regular blood tests to confirm normal metabolic processes.
- if you are taking any of the following medications:
- antacids containing magnesium, aluminium, or calcium. These should preferably be taken 2 hours after or 6 hours before LOMIDA.
- calcium or iron supplements. When taken with food, these can be taken at the same time as LOMIDA, however, when taken on an empty stomach, these should be taken 2 hours after or 6 hours before LOMIDA.
- metformin. LOMIDA should not be used with metformin.
- cladribine.

Children

LOMIDA should not be taken by children under the age of 18 years with a body weight of less than 40 kg.

The safety and efficacy of LOMIDA has not been established in the elderly aged 65 years and older.

LOMIDA 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.

Other medicines and LOMIDA

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

The following medicines interact with LOMIDA in the following ways:

- co-administration of dofetilide and pilsicainide with LOMIDA could lead to increased levels of dofetilide and pilsicainide in your bloodstream
- LOMIDA and medicines containing zalcitabine should not be used together due to similarities in the way they act in the body
- LOMIDA and medicines containing emtricitabine should not be used together due to similarities in the way they act in the body
- co-administration of LOMIDA with medicines containing etravirine has potential to lower LOMIDA levels
- exposure to LOMIDA is decreased when it is co-administered with medicines containing efavirenz
- co-administration of LOMIDA with nevirapine has the potential to decrease levels of LOMIDA in your blood
- co-administration of LOMIDA and atazanavir results in increased levels of LOMIDA in the bloodstream
- co-administration of LOMIDA and medicines containing atazanavir and ritonavir results in increased levels of LOMIDA in the bloodstream
- co-administration of LOMIDA and medicines containing tipranavir and ritonavir results in decreased levels of LOMIDA in the bloodstream
- co-administration of LOMIDA and medicines containing fosamprenavir and ritonavir results in decreased exposure to LOMIDA

- concomitant use of LOMIDA with antacids containing magnesium, aluminium or calcium may lead to decreased levels of LOMIDA in the bloodstream. These antacids should be taken 2 hours after or 6 hours before LOMIDA
- when used concomitantly, calcium supplements and LOMIDA should be taken with food. When taken on an empty stomach, these supplements should be taken 2 hours after or 6 hours before LOMIDA.
- when used concomitantly, iron supplements and LOMIDA should be taken with food. When taken on an empty stomach, these supplements should be taken 2 hours after or 6 hours before LOMIDA.
- when possible, chronic administration of LOMIDA with medicines containing sorbitol or other osmotic acting poly-alcohols or monosaccharide alcohols such as xylitol, mannitol, lactitol, maltitol should be avoided. Your doctor will frequently monitor your HIV-1 viral load when co-administration cannot be avoided.
- concomitant use of metformin with LOMIDA may increase metformin concentrations in the blood
- co-administration of LOMIDA with rifampicin is expected to result in a decrease in LOMIDA concentrations
- concomitant use of trimethoprim/sulphamethoxazole (co-trimoxazole) with LOMIDA is expected to increase LOMIDA levels
- co-administration of LOMIDA with phenytoin, phenobarbital and carbamazepine, used to treat epilepsy, may decrease dolutegravir in the blood
- co-administration with St John's Wort, used to treat depression, may also result in a decrease of dolutegravir in the blood.

LOMIDA with food, drink, and alcohol

LOMIDA can be taken with or without food.

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 LOMIDA.

Pregnancy

Taking LOMIDA at the time of becoming pregnant or during the first six weeks of pregnancy, may increase the risk of a birth defect, called neural tube defect, such as spina bifida (malformed spinal cord).

If it is possible that you could become pregnant, use a reliable form of birth control (contraception) while you are taking LOMIDA. Talk to your doctor about this.

If you are a woman who could become pregnant, your doctor will ask you to take a pregnancy test before you start taking LOMIDA**.**

Tell your doctor immediately if you become pregnant or are planning to become pregnant. Your doctor may need to switch you to another type of medicine if pregnancy is confirmed, while taking LOMIDA.

Breastfeeding

Talk to your doctor if you are breastfeeding your baby. Women who are HIV-positive must not breastfeed because HIV infection can be passed on to the baby in breast milk.

The ingredients in LOMIDA can pass into your breast milk.

Driving and using machines

It has been reported that LOMIDA causes dizziness, therefore the patient should be cautious when driving heavy machinery.

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

3. How to take LOMIDA

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

Always take LOMIDA 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 is one 50/300 mg tablet, taken once daily with or without food, at the same time each day.

Your doctor will tell you how long your treatment with LOMIDA will last. Do not stop treatment because this may cause resistance to the medicine. If you have the impression that the effect of LOMIDA is too strong or too weak, tell your doctor or pharmacist.

The tablets must be swallowed whole with a glass of water.

Do not crush or chew them.

Follow these instructions closely unless your doctor has advised you otherwise.

If you take more LOMIDA than you should

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

There are no specific signs and symptoms which have been identified for the overdose of LOMIDA. An overdose of LOMIDA may manifest the side effects associated with LOMIDA in increased severity. Some of these side effects include:

- upper abdominal pain
- vomiting
- diarrhoea
- rash.

If you forget to take LOMIDA

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

4. Possible side effects

LOMIDA can have side effects.

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

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

- swelling of the hands, feet, face, lips or throat which may cause difficulty swallowing or breathing
- severe itchy, lumpy rash (hives) or nettle rash (urticaria)
- abdominal pain
- feeling tired

- shortness of breath
- weight loss.

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

- suicidal thoughts
- worsening or developing of infections
- diarrhoea or abnormal stools
- vomiting
- anxiety.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- difficulty sleeping (insomnia)
- depression
- abnormal dreams
- headache
- dizziness
- sleepiness
- feeling bloated or having gas
- rash
- itching

- loss of hair (alopecia)
- joint pain
- muscle pain
- a general feeling of weakness
- fever
- Increased liver enzymes such as creatinine phosphokinase (CPK), alanine aminotransferase (ALT), and aspartate aminotransferase (AST) (determined through laboratory tests).

Less frequent side effects:

- anaemia
- low levels of neutrophils (determined through laboratory tests)
- low number of platelets in blood (determined through laboratory tests)
- low red blood cell count (determined through laboratory tests)
- redistribution of body fat
- weakness, numbness and pain in the hands and feet
- tingling sensation in the hands and feet
- inflammation of the pancreas (characterised by abdominal pain, fever, nausea, vomiting)
- increase in levels of amylase in the blood (a protein produced by your pancreas) (determined through laboratory tests)
- abdominal discomfort
- liver disease (hepatitis) or liver failure (determined through laboratory tests).

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: http://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 LOMIDA.

5. How to store LOMIDA

Store all medicines out of reach of children.

- store at or below 25 °C
- do not refrigerate
- store in the original container
- keep the container tightly closed
- do not store in a bathroom
- do not use LOMIDA after the expiry date stated on the container
- return all unused medicines to your pharmacist
- do not dispose unused medicines in drains or sewerage systems. (e.g., toilets).

6. Contents of the pack and other information

What LOMIDA contains

The active substances are dolutegravir 50 mg and lamivudine 300 mg.

The other ingredients are colloidal silicon dioxide, mannitol, microcrystalline cellulose, Opadry Gray YS-1-17506-A, povidone, sodium starch glycolate and sodium stearyl fumarate.

Contents of the film-coating (Opadry Gray) are ferrosoferric oxide/black iron oxide, hypromellose, macrogol, polysorbate 80 and titanium dioxide.

What LOMIDA looks like and contents of the pack

LOMIDA are grey coloured, capsule shaped, biconvex, film-coated tablets debossed with “C” on one side and plain on other side.

LOMIDA film-coated tablets are marketed in HDPE containers; pack sizes are 28’s and 30’s.

Holder of certificate of registration

CIPLA MEDPRO MANUFACTURING (PTY) LTD.

1474 South Coast Road

Mobeni

Durban

4052

Customer care: 080 222 6662

This leaflet was last revised in

20 February 2024

Registration number

54/20.2.8/0642.641

Access to the corresponding Professional Information

To access corresponding Professional Information, scan the QR Code below.

PLACE HOLDER:

The QR Code to be generated and included after approval.

This product has been manufactured under licences from Gilead Sciences, Inc., the Medicines Patent Pool, and ViiV Healthcare. Any other use is not authorised.