Applicant: MSD (Pty) Ltd
APPROVED PATIENT INFORMATION LEAFLET
DELSTRIGO 100 mg/300 mg/245 mg Film-coated Tablets

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

DELSTRIGO® 100 mg/300 mg/245 mg Film-coated Tablets

doravirine/lamivudine/tenofovir disoproxil

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- DELSTRIGO 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 DELSTRIGO is and what it is used for
2. What you need to know before you take DELSTRIGO
3. How to take DELSTRIGO
4. Possible side effects
5. How to store DELSTRIGO
6. Contents of the pack and other information

1. What DELSTRIGO is and what it is used for

DELSTRIGO is used to treat HIV ("Human Immunodeficiency Virus") infection in adults, and adolescents aged 12 years and older weighing at least 35 kg. It belongs to a group of medicines called "antiretroviral medicines".

DELSTRIGO contains the active substances:

- Doravirine - a non-nucleoside reverse transcriptase inhibitor (NNRTI)
- Lamivudine - a nucleoside analogue reverse transcriptase inhibitor (NRTI)
- Tenofovir disoproxil - a nucleoside analogue reverse transcriptase inhibitor (NRTI)

HIV is the virus that causes AIDS ("Acquired Immune Deficiency Syndrome"). You should not take DELSTRIGO if your doctor has told you that the virus causing your infection is resistant to any of the medicines in DELSTRIGO.

How DELSTRIGO works

DELSTRIGO works by preventing HIV from making more viruses in your body. This will help by:

- reducing the amount of HIV in your blood (this is called your "viral load")
- increasing the number of white blood cells called "CD4+ (T)". This can make your immune system stronger. This may reduce your risk of early death or catching infections because your immune system is weak.

2. What you need to know before you take DELSTRIGO

Do not take DELSTRIGO:

- if you are allergic to doravirine, lamivudine or tenofovir disoproxil or any of the other ingredients of this medicine listed in section 6.
- if you are taking any of the following medicines:
  - carbamazepine, oxcarbazepine, phenobarbitone, phenytoin (medicines for seizure)

- rifampicin, rifapentine (medicines for tuberculosis)
- St. John's wort (*Hypericum perforatum*, an herbal remedy used for depression and anxiety) or products that contain it
- mitotane (a medicine to treat cancer)
- enzalutamide (a medicine to treat prostate cancer)
- lumacaftor (a medicine to treat cystic fibrosis)

- if you have moderate or severe kidney disease.

Do not take DELSTRIGO if the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking DELSTRIGO. See also the list in section "Taking other medicines and DELSTRIGO".

Warnings and precautions

Talk to your doctor or pharmacist before taking DELSTRIGO.

Passing HIV to others

HIV is spread by contact with blood or through sexual contact with a person with HIV. You can still pass on HIV when taking DELSTRIGO, although effective therapy lowers the risk. Talk to your doctor about what you can do to avoid infecting other people.

Worsening of hepatitis B infection

If you have both HIV and hepatitis B virus infections, your hepatitis B may get worse if you stop taking DELSTRIGO. You may require blood tests for several months after stopping treatment. Discuss your hepatitis B therapy with your doctor.

New or worsening kidney problems, including kidney failure

This can happen in some people who take DELSTRIGO. Your doctor will do blood tests to check your kidney function before and during treatment with DELSTRIGO.

Bone problems

This can happen in some people who take DELSTRIGO. Bone problems include bone pain, and bone softening or thinning (which may lead to fractures). Joint or muscle pain or muscle weakness may also occur. Your doctor may need to do additional tests to check your bones.

Immune reconstitution inflammatory syndrome

This can happen when you start taking any HIV medicine, including DELSTRIGO. Your immune system may get stronger and begin to fight infections that have been hidden in your body for a long time. Tell your doctor right away if you start having any new symptoms after starting your HIV medicine.

Autoimmune disorders (a condition that occurs when the immune system attacks healthy body tissue) may also occur after you start taking medicines for the treatment of your HIV infection. Autoimmune disorders may occur many months after the start of treatment. If you notice any symptoms of infection or other symptoms such as muscle weakness, weakness beginning in the hands and feet and moving up towards the trunk of the body, palpitations, tremor or hyperactivity, please inform your doctor immediately to seek necessary treatment.

Children and adolescents

Do not give DELSTRIGO to children aged less than 12 years or weighing less than 35 kg. The use of DELSTRIGO in people aged less than 12 years or weighing less than 35 kg has not yet been studied.

Taking other medicines and DELSTRIGO

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

This is because other medicines may affect how DELSTRIGO works and DELSTRIGO might affect the way some other medicines work.

There are some medicines you must not take with DELSTRIGO. See list under “Do not take DELSTRIGO” section.

Talk to your doctor before taking the following medicines with DELSTRIGO as your doctor may need to change the dose of your medicines:

- bosentan (a medicine to treat lung disease)
- dabrafenib (a medicine to treat skin cancer)
- lesinurad (a medicine to treat gout)
- modafinil (a medicine to treat excessive sleepiness)
- nafcillin (a medicine to treat some bacterial infections)
- rifabutin (a medicine to treat some bacterial infections such as tuberculosis)
- telotristat ethyl (a medicine to treat diarrhoea in people with carcinoid syndrome)
- thioridazine (a medicine to treat psychiatric conditions such as schizophrenia).

If your doctor decides you should take these medicines with DELSTRIGO, your doctor will prescribe a 100 mg tablet of doravirine to be taken daily, approximately 12 hours after your dose of DELSTRIGO.

Your doctor may check your blood levels or monitor for side effects if you take the following medicines with DELSTRIGO:

- ledipasvir/sofosbuvir (medicines used to treat hepatitis C infection)
- sirolimus (a medicine used to control your body’s immune response after a transplant)
- sofosbuvir/velpatasvir (medicines used to treat hepatitis C infection)
- tacrolimus (a medicine used to control your body’s immune response after a transplant)
- medicines (usually liquids) containing sorbitol and other sugar alcohols (such as xylitol, mannitol, lactitol or maltitol), if taken regularly.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, talk to your doctor about the risks and benefits of taking DELSTRIGO. It is preferable to avoid the use of DELSTRIGO during pregnancy. This is because it has not been studied in pregnancy and it is not known if DELSTRIGO will harm your baby while you are pregnant. Women with HIV should not breastfeed because HIV can be passed on to babies through breast milk. Talk with your doctor about the best way to feed your baby.

Driving and using machines

Use with caution when driving, riding a bicycle or operating machines if you feel tired, dizzy or sleepy after taking this medicine.

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

Important information about some of the ingredients of DELSTRIGO

DELSTRIGO Tablets contains lactose

If you have been told by your doctor that you have an intolerance to lactose, talk to your doctor before taking this medicine.

3. How to take DELSTRIGO

Always take DELSTRIGO exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. DELSTRIGO is a complete regimen taken as a single tablet for the treatment of HIV infection.

How much to take

The recommended dose is 1 tablet once a day. If you take certain medicines, your doctor may need to change the amount of doravirine you take. See “Other medicines and DELSTRIGO” section for a list of medicines.

Taking DELSTRIGO

- Swallow the tablet whole (do not crush or chew).
- This medicine can be taken with food or between meals.

If you take more DELSTRIGO than you should

Do not take more than the recommended dose. If you take more, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take DELSTRIGO

- It is important that you do not miss or skip doses of DELSTRIGO.
- If you forget a dose, take it as soon as you remember. But if your next dose is due within 12 hours, skip the dose you missed and take the next one at the usual time. Then continue your treatment as before.
- Do not take two doses of DELSTRIGO at the same time to make up for a missed dose.
- If you are not sure what to do, call your doctor or pharmacist.

If you stop taking DELSTRIGO

Do not run out of DELSTRIGO. Refill your prescription or talk to your doctor before your DELSTRIGO is all gone.

If you stop taking DELSTRIGO, your doctor will need to check your health often and do blood tests regularly for several months to check your HIV infection. If you have HIV infection and hepatitis B infection, it is especially important not to stop your DELSTRIGO treatment

without talking to your doctor first. Some patients have had blood tests or symptoms indicating that their hepatitis has worsened after stopping lamivudine or tenofovir disoproxil (two of the three active substances of DELSTRIGO). If DELSTRIGO is stopped your doctor may recommend that you resume hepatitis B treatment. You may need blood tests to check how your liver is working for 4 months after stopping treatment. In some patients with advanced liver disease or cirrhosis, stopping treatment is not recommended as this may lead to worsening of your hepatitis, which may be life-threatening.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

DELSTRIGO can cause side effects.

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

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

- difficulty in breathing
- swelling of the face, lips, tongue or throat.

These are all very serious side effects. If you have them, you may have had a serious reaction to DELSTRIGO. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you have any of the following:

- pain in the chest
- kidney damage, kidney stones, kidney failure, damage to kidney tubule cells, kidney injury, passing a lot of urine

- enlarged liver or fatty liver, yellow skin or eyes, pain in the belly (abdomen) caused by inflammation of the liver
- lactic acidosis (excess lactic acid in the blood).

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

Tell your doctor if you notice any of the following:

Frequent:

- abnormal dreams, difficulty in sleeping (insomnia), headache, dizziness, sleepiness
- cough, nasal symptoms
- feeling sick (nausea), diarrhoea, stomach pain, vomiting, wind (flatulence)
- hair loss, rash
- muscle symptoms (pain, stiffness)
- feeling tired, fever.

Blood tests may also show:

- increased levels in liver enzymes (ALT).

Less frequent:

- nightmares, depression, anxiety, irritability, confusion, suicidal thoughts
- trouble concentrating, memory problems, tingling of hands and feet, stiff muscles, poor quality of sleep
- high blood pressure
- constipation, stomach discomfort, swollen or bloated stomach (abdominal distention), indigestion, soft stools, stomach spasms, frequent bowel movements, inflammation of the pancreas (pancreatitis) (causing stomach pain, vomiting)
- itchiness
- joint pain, breakdown of muscle tissue, muscular weakness

- feeling weak, general feeling of being unwell.

Blood tests may also show:

- decreased number of white blood cells in your blood (neutropenia)
- decreased number of red blood cells in your blood (anaemia)
- decreased levels of platelets in your blood (you may bleed more easily)
- decreased levels phosphate
- decreased levels of potassium in your blood
- increased levels of creatinine in your blood
- increased levels in liver enzymes (AST)
- increased levels of lipase
- increased levels of amylase
- decreased levels of haemoglobin.

The muscle pain, muscle weakness and decreases in potassium or phosphate in the blood may occur due to damage to kidney tubule cells.

- aggression, hallucinations, difficulty adjusting to changes, mood changes, sleep walking
- enlarged tonsils
- feeling of incomplete defecation
- inflammation of the skin due to allergy, redness on the cheeks, nose, chin or forehead, bumps or pimples on the face
- muscle weakness, weakening of the bones (with bone pain and sometimes resulting in fractures)
- feeling thirsty
- feeling cold, pain, thirst.

Blood tests may also show:

- decreased levels of magnesium
- increased levels of creatine phosphokinase.

Frequency unknown:

Blood tests may also show:

- failure of the bone marrow to produce new red blood cells (pure red cell aplasia).

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (whoumc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of DELSTRIGO.

5. How to store DELSTRIGO

- Store at or below 30 °C.
- Store all medicines out of reach of children.
- Do not use DELSTRIGO after the expiry date which is stated on the bottle after EXP.
- The bottle contains a desiccant protecting the tablets from moisture. There may be more than one in the bottle. Keep the desiccant inside the bottle and do not throw away until you have finished taking all of the medicine.
- Keep the bottle tightly closed in order to protect from moisture.

- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What DELSTRIGO contains

- The active substances are 100 mg of doravirine, 300 mg of lamivudine and 245 mg of tenofovir disoproxil (as fumarate).
- The other ingredients are croscarmellose sodium E468; hypromellose acetate succinate; magnesium stearate E470b; microcrystalline cellulose E460; silica; colloidal anhydrous E551; sodium stearyl fumarate. The tablets are film-coated with a coating material containing the following ingredients: carnauba wax E903; hypromellose E464; iron oxide yellow E172; lactose monohydrate; titanium dioxide E171 and triacetin E1518.

What DELSTRIGO looks like and contents of the pack

DELSTRIGO is available as a yellow, oval-shaped, film-coated tablet, and is debossed with the corporate logo and 776 on one side and plain on the other side.

Each carton contains a white high-density polyethylene (HDPE) bottle with a white polypropylene child-resistant closure with silica gel desiccants.

The following pack size is available: 1 bottle with 30 film-coated tablets.

Holder of Certificate of Registration

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