PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

[PRODUCT NAME] 50 mg film coated tablets

Dolutegravir

Contains sugar: Mannitol 144,4 mg per tablet

Read all of this leaflet carefully before you start taking [PRODUCT NAME]

- 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.
- [PRODUCT NAME] 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 [PRODUCT NAME] is and what it is used for

Dolutegravir belongs to a group of anti-retroviral medicines called integrase inhibitors (INIs).

[PRODUCT NAME] is used, in combination with other anti-retroviral medicines (combination therapy), to treat HIV (human immunodeficiency virus) infection in adults.

[PRODUCT NAME] does not cure HIV infection; it reduces the amount of virus in your body, and keeps it at a low level.

2. What you need to know before you take [PRODUCT NAME]

Do not take [PRODUCT NAME] :

- If you are allergic to dolutegravir or any of the other ingredients of [PRODUCT NAME].
- If you are taking dofetilide or pilsicainide (to treat heart conditions),
- If you are taking metformin (to treat type 2 diabetes).
- If you have liver problems.

Warnings and precautions

Take special care with [PRODUCT NAME] :

- If you develop a rash. Some people taking **[PRODUCT NAME] have had allergic reactions (see Possible Side Effects). Contact your doctor immediately**

- You should stop taking [PRODUCT NAME] and contact your doctor immediately if you get other symptoms of an allergic reaction such as fever, fatigue, muscle or joint aches, blisters, sores in your mouth, swelling of your feet or face.

- If you get any other symptoms of other serious infections, usually due to your already weakened immune system. When you start treatment you may find that old, hidden infections (such as tuberculosis) flares up, causing signs and symptoms of inflammation. These symptoms are probably caused by the body's immune system becoming stronger, so that the body starts to fight against these infections.

- If you notice that there is a change in the distribution of fat throughout your body e.g. a hump forming on your back, loss of fat from your face, collection of fat around your abdomen.

- If you experience joint aches and pains, stiffness in your joints or any difficulty with movement, it may be an indication that your bones are being damaged.

- If you are taking any other medicines even if they are non-prescription.

- **Keep in touch with your doctor, and do not stop taking [PRODUCT NAME]** without your doctors advise.

While you are taking [PRODUCT NAME], you will need regular blood tests.

For as long as you are taking [PRODUCT NAME], your doctor will arrange regular blood tests to check for side effects. There is more information about these side-effects in this leaflet. See **Possible Side effects.**

Combination antiretroviral therapy may cause changes in body shape due to changes in fat distribution. These may include loss of fat from legs, arms and face, increased fat in the abdomen (belly) and other internal organs, breast enlargement and fatty lumps on the back of the neck ('buffalo hump'). Contact your doctor if you notice changes in body fat.

Protect other people

HIV infection is spread by sexual contact with someone who has the infection, or by transfer of infected blood (for example, by sharing injection needles). You can still pass on HIV when taking [PRODUCT NAME]. Discuss with your doctor the precautions needed to avoid infecting other people. To protect other people from becoming infected with HIV:

- **Use a condom** when you have oral or penetrative sex.
- **Do not risk blood transfer** – for example, don't share needles.

Other medicines and [PRODUCT NAME]

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

Do not take **[PRODUCT NAME]** with these medicine:

- Dofetilide or pilsicainide, to treat **heart conditions.**
- Metformin, to treat **diabetes.**

Dolutegravir can also affect how some other medicines work. Tell your doctor if you are taking any of the medicines in the following list:

- medicines called **antacids,** to treat indigestion and heartburn. Take dolutegravir 2 hours before or 6 hours after you take antacid.
- calcium supplements and iron supplements. Take dolutegravir 2 hours before or 6 hours after you take a **calcium supplement or iron supplement.**
- etravirine, efavirenz, fosamprenavir/ritonavir, nevirapine or tipranavir/ritonavir, to treat **HIV infection**
- rifampicin, to treat **tuberculosis (TB)** and other bacterial infections
- phenytoin and phenobarbitone, to treat **epilepsy**
- oxcarbazepine and carbamazepine, to treat **epilepsy** or **bipolar disorder**

St. John's wort (*Hypericum perforatum*), a herbal remedy

[PRODUCT NAME] with food and drink

[PRODUCT NAME] can be taken with or without food.

Pregnancy, breast-feeding and fertility

If you are pregnant, think you may be pregnant, or if you are planning to have a baby:

→ **Talk to your doctor** about the risks and benefits of taking [PRODUCT NAME].

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

If you could get pregnant while receiving [PRODUCT NAME]:

→ **Talk to your doctor** and discuss whether there is a need for contraception, such as condom or pills.

Tell your doctor immediately if you become pregnant or are planning to become pregnant. Your doctor will review your treatment. Do not stop taking [PRODUCT NAME] without consulting your doctor, as this may harm you and your unborn child.

Breast-feeding

Women who are HIV-positive must not breast-feed because the HIV infection can be passed on to the baby in breast milk.

A small amount of the ingredient in [PRODUCT NAME] can pass into your breast milk.

If you are breast-feeding, or thinking about breast-feeding:

→ **Talk to your doctor immediately.**

Driving and using machines

[PRODUCT NAME] can make you dizzy and have other side effects that make you less alert. Don't drive or use machines unless you are sure you are not affected.

3. How to take [PRODUCT NAME]

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

Always take **[PRODUCT NAME]** exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

• The usual dose of [PRODUCT NAME] is one 50 mg tablet, once a day;

Your doctor will decide on the correct dose of [PRODUCT NAME] for you.

Swallow the tablets whole with a full glass of water.

[PRODUCT NAME] can be taken with or without food.

Your doctor will tell you how long your treatment with [PRODUCT NAME] will last. Do not stop treatment unless your doctor advises you to.

If you have the impression that the effect of [PRODUCT NAME] is too strong or too weak, tell your doctor or pharmacist.

If you take more [PRODUCT NAME] 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 [PRODUCT NAME]

If you miss a dose, take it as soon as you remember, but if it is within 4 hours of your next dose, skip the dose you missed and take the next one at the usual time. Then continue your treatment as before. **Do not take a double dose** to make up for a missed dose.

Effects when treatment with [PRODUCT NAME] is stopped:

Take **[PRODUCT NAME]** for as long as your doctor recommends. Don't stop unless your doctor advises you to.

To control your HIV infection, and to stop your illness from getting worse, you must keep taking all your medicines, unless your doctor tells you to stop taking any.

4. Possible side effects

[PRODUCT NAME] can have side effects.

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

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

Less frequent

- Allergic reactions. Signs include rash, swelling, sometimes of the face or mouth, causing difficulty in breathing, muscle or joint aches

These are a very serious side effects. If you have them, you may have had a serious allergic reaction to **[PRODUCT NAME].** 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:

Less frequent

- inflammation of the liver (hepatitis)
- an inflammatory condition (immune reconstitution syndrome
  or 'IRIS' (development of other inflammatory reactions or infections when you begin treatment with **[PRODUCT NAME] -** Symptoms usually include fever, plus some of the following: headache, stomach ache, difficulty breathing**)**

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

Tell your doctor if you notice any of the following:

<u>Frequent side effects:</u>

- headache

- diarrhea
- feeling sick (nausea)
- rash
- itching (pruritus)
- being sick (vomiting)
- stomach pain (upper abdominal pain)
- difficulty in sleeping (insomnia)
- dizziness
- abnormal dreams
- lack of energy (fatigue)
- wind (flatulence)

Less frequent side effects:

- abdominal pain,
- abdominal discomfort.
- allergic reactions,
- inflammation of the liver usually noticed by yellowing of your skin and nails,
- suicide attempts or thoughts about suicide.

Laboratory abnormalities

- increase in bilirubin (a substance produced by the liver) in the blood
- an increase in the level of enzymes produced in the muscles
  (creatine phosphokinase, creatinine)

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.

By reporting side effects, you can help provide more information on the safety of [PRODUCT NAME].

5. How to store [PRODUCT NAME]

Store all medicines out of reach of children.

Store at or below 25 °C.

Keep in the original container until required for use.

Keep the container tightly closed.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewage systems (e.g. toilet)

6. Contents of the pack and other information

What [PRODUCT NAME] contains

The active ingredient is 50 mg dolutegravir (as dolutegravir sodium).

The other ingredients are: Magnesium stearate, mannitol, microcrystalline cellulose, opadry II (brown), povidone, sodium starch glycollate, sodium stearyl fumarate, talc.

Coating material: opadry II (brown): Iron oxide yellow, iron oxide red, macrogol/peg, polyvinyl alcohol-part- hydrolysed, talc, titanium dioxide

Contains sugar: 144,4 mg mannitol.

What [PRODUCT NAME] looks like and contents of the pack

Light brown to brown film coated, caplet shaped tablets debossed with "RL75" on one side and breakline on the other side.

Contents of the pack:

The tablets are packed in HDPE Bottles containing 28, 30 and 90 Tablets.

HDPE Bottles can be supplied with or without carton.

Holder of Certificate of Registration

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