PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

DALIMUNE, 50 mg Film-coated tablets.

dolutegravir

Contains sugar: mannitol (145 mg/tablet).

Read all of this leaflet carefully before you start taking DALIMUNE.

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

1. What DALIMUNE is and what it is used for

DALIMUNE is used to treat HIV (Human immunodeficiency virus) infection in adults in combination with other anti-retroviral medicines (combination therapy).

DALIMUNE does not cure HIV infection; it reduces the amount of virus in your body, and keeps it at low level. As a result of that, it also increases the CD4 cell count in your blood. CD4 cells are a type of white blood cell that helps your body fight infection.

2. What you need to know before you take DALIMUNE

Do NOT take DALIMUNE if you:

- Are allergic (hypersensitive) to dolutegravir, or any of the other ingredients in DALIMUNE **(listed in section 6**)
- If you are taking other medicine called dofetilide or pilsicainide (to treat heart conditions)
- if you are taking a medicine called metformin (to treat diabetes)
- if you have moderate or severe liver disease.

Warnings and precautions

Take special care with DALIMUNE

- if you develop a rash. Some people taking DALIMUNE have had allergic reactions including tiredness, muscle or joint pain, red eyes (conjunctivitis), sores in your mouth, blisters, swelling of your face, hands, feet, area around the eyes, yellow discoloration of the skin, vomiting and abdominal pain.
- if you get any symptoms of infection while you are taking DALIMUNE

  People with advanced HIV infection (AIDS) have weak immune systems and are more likely to develop serious infections. When these people start treatment, they may not find that old hidden infections (such as tuberculosis) flare 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 these infections.
- Keep in touch with your doctor, and do not stop taking DALIMUNE without your doctor's advice.

HIV can still be transmitted despite taking DALIMUNE.

DALIMUNE does not cure HIV infection; it reduces the amount of virus in your body.

While you are taking DALIMUNE, you will need regular blood tests.

For as long as you are taking DALIMUNE 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**.

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). DALIMUNE will not stop you passing HIV infection on to 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 DALIMUNE

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

Do not take DALIMUNE with the following medicines:

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

Some medicines can affect how DALIMUNE works or make it more likely that you will have side effects. These include:

- Medicines called antacids, to treat indigestion and heartburn. Do not take an antacid during the 6 hours before you take DALIMUNE**,** or for at least 2 hours after you take it.

- Calcium and iron supplements. Do not take a calcium or iron supplement during the 6 hours before you take DALIMUNE**,** or for at least 2 hours after you take it.
- Etravirine, efavirenz, fosamprenavir/ritonavir, nevirapine or tipranavir/ritonavir, to treat HIV infection
- Rifampicin, to treat tuberculosis
- Phenytoin and phenobarbital, to treat epilepsy
- Oxcarbamazepine and carbamazepine, to treat epilepsy and bipolar disorder
- St. John's wort *(Hypericum perforatum,* a herbal remedy used for deoression

Tell your doctor or pharmacist if you are taking any of these. Your doctor may decide to adjust your dose or that you need extra check-ups.

DALIMUNE with food, drink, and alcohol

DALIMUNE can be taken with or without food.

Pregnancy, breastfeeding, and fertility

If you are a woman who is able to have children, you should be counselled about the potential risk of neural tube defects with dolutegravir.

A pregnancy test should be performed before you start taking DALIMUNE, if you are able to bear children, to exclude the unintentional use of DALIMUNE during the first trimester of pregnancy.

If you plan on becoming pregnant, your doctor will need to discuss the risks and benefits of starting or continuing treatment with DALIMUNE versus another medicine regimen.

It should be noted that the use of dolutegravir, as contained in DALIMUNE, was

associated with a small increase in the likelihood of neural tube defects (Birth defects) compared to non-dolutegravir regimens. Most neural tube defects occur within the first 4 weeks of pregnancy which is approximately 6 weeks after your last menstrual cycle (period).

If you fall pregnant and are taking dolutegravir, as contained in DALIMUNE, the benefits and risks of continuing dolutegravir, as contained in DALIMUNE, versus switching to another medicine regimen should be discussed with you by your doctor.

Dolutegravir, as contained in DALIMUNE, may be used in the second and third trimester of pregnancy when the expected benefit outweighs the potential risk to the foetus.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist, or other healthcare professional for advice before taking this medicine.

Driving and using machines

DALIMUNE can make you dizzy and have other side effects that make you less alert. Do not drive or use machines unless you are sure you are not affected.

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

DALIMUNE contains mannitol

DALIMUNE contains mannitol and may have a laxative effect.

3. HOW TO TAKE DALIMUNE

- Do not share medicines prescribed for you with any other person.
- Always take DALIMUNE exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
- The usual dose of DALIMUNE is one 50 mg tablet, once a day.
- Swallow the tablet with some liquid.
- DALIMUNE can be taken with or without food.

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

- Do not stop treatment unless your doctor advises you to.
- If you have the impression that the effect of DALIMUNE is too strong or too weak, tell your doctor or pharmacist.

If you take more DALIMUNE 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. If possible, show them the DALIMUNE pack.

If you forget to take DALIMUNE

If you miss a dose, take it as soon as you remember. But if your next dose is due within 4 hours, 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 the dose you missed.

If you stop taking using DALIMUNE

Take DALIMUNE for as long as your doctor recommends. Do not stop unless your doctor advises you to.

4. Possible side effects

DALIMUNE can have side effects.

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

It is very important to talk to your doctor about any changes in your health.

Some side effects may only be seen in your blood tests and may not appear immediately after you start taking DALIMUNE. If you get any of these effects and if they are severe, your doctor may advise you to stop taking DALIMUNE.

As well as the effects listed below for DALIMUNE, other conditions can develop during combination therapy for HIV (see: **Take special care with DALIMUNE**).

If any of the following happens, see a doctor immediately or go to the casualty department at your nearest hospital:

Allergic reactions:

Less frequent: skin rash, a high temperature (fever), lack of energy (fatigue), swelling, sometimes of the face and mouth (angioedema), causing difficulty in breathing, muscle, or joints aches.

These are all very serious side effects. See a doctor as soon as possible.

Your doctor may decide to carry out tests on your liver, kidneys or blood and may tell you to stop taking DALIMUNE**.**

Frequent: headache, diarrhoea, feeling sick (nausea), rash, itching (pruritus), being sick (vomiting), stomach pain (upper abdominal pain), difficulty in sleeping

	(insomnia), dizziness, abnormal dreams, feeling of deep sadness and unworthiness (depression), lack of energy (fatigue), wind (flatulence)
Less frequent:	Inflammation of the liver (hepatitis), an inflammatory condition which may develop as the immune system becomes stronger (immune reconstitution syndrome or 'IRIS'), suicidal thoughts, allergic reaction (hypersensitivity) (see earlier in this section for more details), stomach (abdominal) discomfort

Side effects that may show up in blood tests:

	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).

Tell your doctor or pharmacist if any of the side effects listed becomes severe or troublesome, or if you notice any side effects not listed in this leaflet.

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. By reporting side effects, you can help provide more information on the safety of DALIMUNE.

5. How to store DALIMUNE

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Store at or below 30 °C.

Do not use after the expiry date stated on the label and 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 DALIMUNE contains

The active substance is 50 mg of dolutegravir (as dolutegravir sodium).

The other ingredients are:

Tablet core: Colloidal silicon dioxide*,* mannitol, microcrystalline cellulose, povidone, sodium starch glycolate, sodium stearyl fumarate.

Tablet coating: Opadry II (Iron oxide red/yellow, macrogol/polyethylene glycol, polyvinyl alcohol-part hydrolysed, talc, titanium dioxide.

What DALIMUNE looks like and contents of the pack

Brown coloured round shaped biconvex film coated tablet debossed with “C 50” on one side and plain on other side.

DALIMUNE tablets are packed in 50 cc white high-density polyethylene (HDPE) bottle with 33 mm child resistant cap (CRC) with heat seal 130-20 liner containing 28 or 30 tablets with or without a cardboard carton.

Holder of Certificate of Registration

CIPLA MEDPRO MANUFACTURING (PTY) LTD.

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4052

Customer care number: 080 2226662

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