PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

DEPLATT 75 mg film-coated tablet

Clopidogrel hydrogen sulfate

Contains Lactose and mannitol

Read all of this leaflet carefully before you start taking given DEPLATT

- 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.
- **DEPLATT** 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 DEPLATT is and what it is used for

Platelets are small structures in the blood and by clumping together they are responsible for blood clotting. Blood clots (thrombi) can easily form in hardened

blood vessels (arteries), which can increase the risk of a stroke or a heart attack. **DEPLATT** belongs to a group of medicines that prevent platelets from clumping and therefore prevents blood clots from forming.

You have been prescribed **DEPLATT** because you have either previously experienced a heart attack or stroke, or you have a circulatory problem in which narrowed blood vessels (arteries) reduce blood flow to your limbs. **DEPLATT** is also prescribed when you have a condition known as hardening of the arteries (atherosclerosis). Atherosclerosis results in a narrowing of the blood vessels (arteries) and an increased risk of blood clots (thrombi). **DEPLATT** is taken to prevent blood clots forming in the hardened arteries thus reducing the risk of a stroke or a heart attack.

2. What you need to know before you take DEPLATT

Do not take DEPLATT:

- If you are hypersensitive (allergic) to clopidogrel or any of the other ingredients of **DEPLATT** (listed in section 6).
- If you have a medical condition that is currently causing bleeding such as a stomach ulcer or bleeding within the brain
- If you suffer from severe liver disease
- If you suffer from low platelet count (thrombocytopenia)
- If you suffer from low white blood cell count (neutropenia)
- If you suffer from a blood disorder that affects your body's ability to form new blood cells (haematopoietic disorder)
- If you suffer from a blood disorder that makes you prone to internal bleeding (bleeding inside any tissues, organs or joints of your body) (haemorrhagic disorder)

- Use in children is not recommended as there is not sufficient data for the use of **DEPLATT**
- If you are pregnant or breastfeeding your baby.

Warnings and precautions

Special care should be taken with **DEPLATT**:

- If you have had a recent serious injury
- If you have recently undergone surgery (including dental)
- If you have recently received spinal anaesthesia or anaesthesia which produced loss of sensation below the waist (epidural anaesthesia)
- If you have recently received spinal anaesthesia or anaesthesia which produced loss of sensation below the waist (epidural anaesthesia)
- If you have a blood disorder that makes you prone to internal bleeding (bleeding inside any tissues, organs or joints of your body)
- If you have a medical condition that puts you at risk of internal bleeding (such as a stomach ulcer or bleeding within the brain)
- If you will be having surgery (including dental) in the next 7 days
- If you are taking medicines that are used to thin your blood or for inflammation such as aspirin, heparin, warfarin and NSAIDs. This includes all medications, even those which you have purchased yourself without a medical prescription
- If you have kidney or liver disease.

While you are taking DEPLATT:

- You should tell your doctor immediately if you develop a medical condition (also known as Thrombotic Thrombocytopenic Purpura or TTP) that includes fever and bruising under the skin that may appear as purplish spots, with or without unexplained extreme tiredness, headaches, confusion, slurred speech,

yellowing of the skin or eyes (jaundice) (see POSSIBLE SIDE EFFECTS)

- If you cut or injure yourself, it may take slightly longer than usual for bleeding to stop. This is linked to the way your medicine works. For minor cuts and injuries e.g. cutting yourself shaving, this is of no concern. However, if you are in any doubt at all, you should contact your doctor immediately.

Other medicines and DEPLATT

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

You should especially tell your doctor if you are taking:

- Aspirin (acetylsalicylic acid) for prolonged periods, except when it has been specifically recommended by your doctor
- Other medicinal products used to reduce blood clotting (thrombolytics), warfarin and heparin
- Medicines (glycoprotein IIb/IIIa inhibitors) used to prevent clotting following invasive heart procedures, surgery where blood vessels have been unblocked (angioplasty) or heart attacks
- Non-Steroidal Anti-Inflammatory Medicinal products (medicinal products used to treat painful and/or inflammatory conditions of muscles or joints) when taken for prolonged periods
- Omeprazole and esomeprazole or cimetidine (medicines to treat upset stomach)
- Fluconazole, voriconazole, ciprofloxacin or chloramphenicol (medicines to treat bacterial and fungal infections)
- Fluoxetine, fluvoxamine or moclobemide (medicines to treat depression)
- Carbamazepine, phenytoin or oxcarbazepine (medicines to treat some forms of epilepsy)

- Ticlopidine (antiplatelet agent)
- Tolbutamide (medicine to treat diabetes, when you have high levels of sugar in your blood)
- Tamoxifen (medicine to treat breast cancer and infertility (when you cannot have children) in women)
- Fluvastatin (medicine to treat high cholesterol, a type of fat in your blood)

Taking DEPLATT with food and drink:

DEPLATT may be taken with or without food.

Pregnancy and breastfeeding

Do not take DEPLATT if you are pregnant or if you are breastfeeding your baby.
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 this medicine.

Driving and using machines

It is not always possible to predict to what extent **DEPLATT** 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 **DEPLATT** affects them.
DEPLATT is unlikely to affect your ability to drive or use machinery.

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

DEPLATT contains mannitol (a sugar that comes from plants), which may have a mild laxative effect.

3. How to take DEPLATT

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

Always take **DEPLATT** exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults (including the elderly):

The usual dose is one 75 mg tablet of **DEPLATT** per day, with or without food. You should take your medicine regularly and at the same time each day.

If you take more DEPLATT than you should

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

An overdose of DEPLATT may lead to longer bleeding time than usual in the event that you cut or injure yourself.

If you forget to take DEPLATT

If you forget to take a dose of **DEPLATT**, but remember within 12 hours of your usual time, take your tablet straightaway and then take your next tablet at the normal time. If you forget for more than 12 hours simply take the next single dose at the usual time.

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

If you stop taking DEPLATT

Do not stop the treatment unless your doctor tells you so. Contact your doctor or pharmacist before stopping.

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

4. Possible side effects

DEPLATT can have side effects.

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

If any of the following happens, stop taking **DEPLATT** 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
- Yellowing of the skin and eyes, also called jaundice
- Bleeding which appears under the skin as red pinpoint dots and/or confusion and fever
- Bleeding in the stomach or bowels, bleeding inside the head or from an operation wound; bleeding in the eye, the lung or the joints.

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

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

Frequent

- Bleeding in the stomach or bowels; haematoma (unusual bleeding or bruising under the skin, solid swelling of clotted blood); nose bleed.

Less frequent

- Deficiency of platelets in the blood (which results in bruising and slow blood clotting); deficiency of all blood cell types; reduction in the ability of blood to clot; jaundice; abnormal liver function blood tests; breathing difficulties sometimes associated with cough; decrease in blood pressure; confusion; hallucinations; inflammation of the pancreas or the lining of the large intestine; liver failure; blood in the urine; inflammation of the kidney.

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

Tell your doctor if you notice any of the following:

Frequent:

- Diarrhoea; abdominal pain; indigestion or heartburn; bruising; bleeding at puncture site.

Less frequent:

- Reduction in the number of white blood cells; headache; inflammation of a blood vessel or of the lining of the stomach; stomach ulcer; vomiting; nausea; constipation; excessive gas in the stomach or intestines; rashes; itching; dizziness; sensation of tingling and numbness; vertigo (a sensation of whirling and loss of balance); joint stiffness; muscular pain; scarring of the lung; change in taste of food; inflammation of the lining of the mouth;

fluid filled blisters on the skin; swelling of the deep layers of the skin; eczema (patches of skin become rough and inflamed with blister which cause itching and bleeding); fever; bleeding time prolonged.

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. 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 **DEPLATT**.

5. How to store DEPLATT

Store all medicines out of reach of children.

- Store at or below 30 °C
- Store in the original package
- Keep blister in outer carton until required for use
- Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What DEPLATT contains

- The active substance is clopidogrel hydrogen sulfate equivalent to 75 mg clopidogrel.
- The other ingredients are colloidal anhydrous silica, ferric oxide red,

hydrogenated castor oil, hydroxy propyl cellulose, hypromellose 6 cps, lactose, magnesium stearate, mannitol, microcrystalline cellulose, polyethylene glycol 6000, titanium dioxide.

What DEPLATT looks like and contents of the pack

DEPLATT (Clopidogrel 75 mg) tablets are light pink coloured, round, beveled edge, biconvex, engraved film-coated tablets, plain on both the sides.

Printed cardboard cartons with silver coloured cold forming blister aluminium foil (OPA 25 µ / Aluminium 45 µ PVC 60 µ), sealed with aluminium foil (0,025 x 132 mm) with heat seal lacquer coating blisters containing 10, 30 or 100 tablets. Each blister strip contains 10 tablets.

Holder of Certificate of Registration

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This leaflet was last revised in

2 September 2022

Registration number

A45/8.2/1031

Access to the corresponding Professional Information

PI can be found in the carton with this Information Leaflet