

## PATIENT INFORMATION LEAFLET

### 1 SCHEDULING STATUS

2 **S3**

3 **DEPLATT 75 mg film-coated tablet**

4 **Clopidogrel hydrogen sulfate**

5 **Contains Lactose and mannitol**

6

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

- 8 • Keep this leaflet. You may need to read it again.
- 9 • If you have further questions, please ask your doctor, pharmacist, nurse or other health
- 10 care provider.
- 11 • **DEPLATT** has been prescribed for you personally and you should not share your
- 12 medicine with other people. It may harm them, even if their symptoms are the same as
- 13 yours.

14

### 15 **What is in this leaflet**

- 16 1. What **DEPLATT** is and what it is used for
- 17 2. What you need to know before you take **DEPLATT**
- 18 3. How to take **DEPLATT**
- 19 4. Possible side effects
- 20 5. How to store **DEPLATT**
- 21 6. Contents of the pack and other information

22

### 23 **1. What DEPLATT is and what it is used for**

24 Platelets are small structures in the blood and by clumping together they are responsible for

25 blood clotting. Blood clots (thrombi) can easily form in hardened blood vessels (arteries),

26 which can increase the risk of a stroke or a heart attack. **DEPLATT** belongs to a group of

27 medicines that prevent platelets from clumping and therefore prevents blood clots from  
28 forming.

29

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

37

## 38 **2. What you need to know before you take DEPLATT**

### 39 **Do not take DEPLATT:**

- 40 • If you are hypersensitive (allergic) to clopidogrel or any of the other ingredients of  
41 **DEPLATT** (listed in section 6).
- 42 • If you have a medical condition that is currently causing bleeding such as a stomach ulcer  
43 or bleeding within the brain
- 44 • If you suffer from severe liver disease
- 45 • If you suffer from low platelet count (thrombocytopenia)
- 46 • If you suffer from low white blood cell count (neutropenia)
- 47 • If you suffer from a blood disorder that affects your body's ability to form new blood cells  
48 (haematopoietic disorder)
- 49 • If you suffer from a blood disorder that makes you prone to internal bleeding (bleeding  
50 inside any tissues, organs or joints of your body) (haemorrhagic disorder)
- 51 • Use in children is not recommended as there is not sufficient data for the use of **DEPLATT**
- 52 • If you are pregnant or breastfeeding your baby.

53 **Warnings and precautions**

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

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

70

71 While you are taking DEPLATT:

- 72 • You should tell your doctor immediately if you develop a medical condition (also known  
73 as Thrombotic Thrombocytopenic Purpura or TTP) that includes fever and bruising under  
74 the skin that may appear as purplish spots, with or without unexplained extreme tiredness,  
75 headaches, confusion, slurred speech, yellowing of the skin or eyes (jaundice) (see  
76 POSSIBLE SIDE EFFECTS)
- 77 • If you cut or injure yourself, it may take slightly longer than usual for bleeding to stop. This  
78 is linked to the way your medicine works. For minor cuts and injuries e.g. cutting yourself  
79 shaving, this is of no concern. However, if you are in any doubt at all, you should contact

80 your doctor immediately.

81

82 **Other medicines and DEPLATT**

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

85 You should especially tell your doctor if you are taking:

- 86 • Aspirin (acetylsalicylic acid) for prolonged periods, except when it has been specifically  
87 recommended by your doctor
- 88 • Other medicinal products used to reduce blood clotting (thrombolytics), warfarin and  
89 heparin
- 90 • Medicines (glycoprotein IIb/IIIa inhibitors) used to prevent clotting following invasive  
91 heart procedures, surgery where blood vessels have been unblocked (angioplasty) or  
92 heart attacks
- 93 • Non-Steroidal Anti-Inflammatory Medicinal products (medicinal products used to treat  
94 painful and/or inflammatory conditions of muscles or joints) when taken for prolonged  
95 periods
- 96 • Omeprazole and esomeprazole or cimetidine (medicines to treat upset stomach)
- 97 • Fluconazole, voriconazole, ciprofloxacin or chloramphenicol (medicines to treat bacterial  
98 and fungal infections)
- 99 • Fluoxetine, fluvoxamine or moclobemide (medicines to treat depression)
- 100 • Carbamazepine, phenytoin or oxcarbazepine (medicines to treat some forms of  
101 epilepsy)
- 102 • Ticlopidine (antiplatelet agent)
- 103 • Tolbutamide (medicine to treat diabetes, when you have high levels of sugar in your  
104 blood)
- 105 • Tamoxifen (medicine to treat breast cancer and infertility (when you cannot have  
106 children) in women)

107 • Fluvastatin (medicine to treat high cholesterol, a type of fat in your blood)

108

109 **Taking DEPLATT with food and drink:**

110 DEPLATT may be taken with or without food.

111

112 **Pregnancy and breastfeeding**

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

114 If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a  
115 baby, please consult your doctor, pharmacist or other health care provider for advice before  
116 taking this medicine.

117

118 **Driving and using machines**

119 It is not always possible to predict to what extent **DEPLATT** may interfere with the daily  
120 activities of a patient. Patients should ensure that they do not engage in the above activities  
121 until they are aware of the measure to which **DEPLATT** affects them. **DEPLATT** is unlikely  
122 to affect your ability to drive or use machinery.

123

124 **DEPLATT** tablets contain lactose.

125 If you have been told by your doctor that you have an intolerance to some sugars, contact  
126 your doctor before taking this medicinal product.

127

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

130

131 **3. How to take DEPLATT**

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

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

135 Adults (including the elderly):

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

138

139 **If you take more DEPLATT than you should**

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

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

144

145 **If you forget to take DEPLATT**

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

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

150

151 **If you stop taking DEPLATT**

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

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

156

157 **4. Possible side effects**

158 **DEPLATT** can have side effects.

159

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

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

- 165 • Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause  
166 difficulty in swallowing or breathing
- 167 • Rash or itching
- 168 • Fainting
- 169 • Yellowing of the skin and eyes, also called jaundice
- 170 • Bleeding which appears under the skin as red pinpoint dots and/or confusion and fever
- 171 • Bleeding in the stomach or bowels, bleeding inside the head or from an operation  
172 wound; bleeding in the eye, the lung or the joints.

173

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

176

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

179 *Frequent*

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

182

183 *Less frequent*

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

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

191

192 Tell your doctor if you notice any of the following:

193 Frequent:

194 • Diarrhoea; abdominal pain; indigestion or heartburn; bruising; bleeding at puncture  
195 site.

196 Less frequent:

197 • Reduction in the number of white blood cells; headache; inflammation of a blood  
198 vessel or of the lining of the stomach; stomach ulcer; vomiting; nausea; constipation;  
199 excessive gas in the stomach or intestines; rashes; itching; dizziness; sensation of  
200 tingling and numbness; vertigo (a sensation of whirling and loss of balance); joint  
201 stiffness; muscular pain; scarring of the lung; change in taste of food; inflammation of  
202 the lining of the mouth; fluid filled blisters on the skin; swelling of the deep layers of  
203 the skin; eczema (patches of skin become rough and inflamed with blister which  
204 cause itching and bleeding); fever; bleeding time prolonged.

205

206 Side effects with frequency not known (frequency cannot be estimated from the available  
207 data):

208 Insulin autoimmune syndrome (IAS) is a rare endocrine disorder of persistent low blood sugar  
209 symptoms. Your doctor will order blood tests to confirm this diagnosis.

210

211 If you notice any side effects not mentioned in this leaflet, please inform your doctor or  
212 pharmacist.

213

#### 214 **Reporting of side effects**

215 If you get side effects, talk to your doctor or pharmacist. You can also report side effects to  
216 SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under  
217 SAHPRA's publications:

218 <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help  
219 provide more information on the safety of **DEPLATT**.

220

## 221 **5. How to store DEPLATT**

222 Store all medicines out of reach of children.

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

228

## 229 **6. Contents of the pack and other information**

### 230 **What DEPLATT contains**

- 231 • The active substance is clopidogrel hydrogen sulfate equivalent to 75 mg clopidogrel.
- 232 • The other ingredients are colloidal anhydrous silica, ferric oxide red, hydrogenated castor  
233 oil, hydroxy propyl cellulose, hypromellose 6 cps, lactose, magnesium stearate, mannitol,  
234 microcrystalline cellulose, polyethylene glycol 6000, titanium dioxide.

235

### 236 **What DEPLATT looks like and contents of the pack**

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

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

242 **Holder of Certificate of Registration**

243 Trinity Pharma (Pty) Ltd.

244 106, 16<sup>th</sup> Road, Building 2

245 Midrand, Johannesburg, 1686

246 South Africa

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248 **This leaflet was last revised in**

249 19 December 2023

250

251 **Registration number**

252 A45/8.2/1031

253

254 **Access to the corresponding Professional Information**

255 PI can be found in the carton with this Information Leaflet