PATIENT INFORMATION LEAFLET (APPROVED)

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SCHEDULING STATUS:

S3

CLOPIDOGREL 75 mg PD film coated tablets.

Clopidogrel

CLOPIDOGREL 75 mg PD contains sugar (each tablet contains lactose monohydrate - 108,125 mg)

Read all of this leaflet carefully before you start taking CLOPIDOGREL 75 mg PD

- 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 healthcare provider.
- CLOPIDOGREL 75 mg PD 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

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1. What CLOPIDOGREL 75 mg PD is and what it is used for

CLOPIDOGREL 75 mg PD belongs to a group of medicines called antiplatelet medicinal products.

Platelets are very small structures in the blood which clump together during blood clotting.

CLOPIDOGREL 75 mg PD is used:

- to lessen the chance of heart attack or stroke. It is given to adults who have already had a heart attack or stroke or to those with other blood circulation problems, (including hardening of the arteries) that could lead to a stroke or heart attack
- if you have experienced a severe type of chest pain known as ‘unstable angina’ or ‘myocardial infarction’ (heart attack). For the treatment of this condition your doctor may have placed a stent in the blocked or narrowed artery to restore effective blood flow. You may also be given acetylsalicylic acid (aspirin - to prevent blood clotting) by your doctor.

A heart attack or stroke may occur when a blood vessel in the heart or brain is blocked by a blood clot. CLOPIDOGREL 75 mg PD reduces the chance that a harmful blood clot will form by preventing certain cells in the blood from clumping together.

2. What you need to know before you take CLOPIDOGREL 75 mg PD

Do not take CLOPIDOGREL 75 mg PD:

- if you are hypersensitive (allergic) to clopidogrel, or to any of the ingredients of CLOPIDOGREL 75 mg PD (see section 6)
- if you have bleeding problems (such as bleeding stomach ulcer or increased bleeding tendencies that characterise platelet dysfunction- reduction in blood platelets which increases risk of bleeding and bruising)
- CLOPIDOGREL 75 mg PD should not be given to patients younger than 18 years
- if you are pregnant or breastfeeding your baby (see Pregnancy and breastfeeding)
- if you have liver problems
- if you have been diagnosed with haemophilia (a medical condition in which the ability of the blood to clot is severely reduced, causing you to bleed severely from even a slight injury), either hereditary or as a result of previously taking this medicine.

Warnings and precautions

Take special care / Special care should be taken with CLOPIDOGREL 75 mg PD:

- if you have had a clot in an artery of your brain (ischaemic stroke) which occurred in the last seven days

- if you are going to have surgery or have dental work done. CLOPIDOGREL 75 mg PD may increase the risk of serious bleeding during surgery or some kind of dental work. Therefore, treatment may have to be stopped about 7 days before the operation or dental work is done
- if you have a risk of haemorrhage (bleeding) such as:
  - a medical condition that puts you at risk of internal bleeding (such as a stomach ulcer)
  - a blood disorder that makes you prone to internal bleeding (bleeding inside any tissue, organs or joints of your body)
  - a recent serious injury
  - a recent surgery (including dental)
  - a planned surgery (including dental) in the next seven days
  - a planned spinal, epidural anaesthetic or a lumbar puncture in the next seven days
- if you have thrombotic thrombocytopenic purpura (TTP) - a serious blood disorder (that includes symptoms such as fever and bruising under the skin that may appear as red pinpoint dots, with or without unexplained extreme tiredness, confusion, yellowing of the skin or eyes (jaundice))
- if you develop a condition called acquired haemophilia (causing you to bleed severely from even a slight injury) your doctor may discontinue this medicine
- if you are hypersensitive (allergic) to other anti-platelet medicines called thienopyridine (such as ticlopidine, prasugrel), used to prevent blood clots

- if you have insulin autoimmune syndrome (a rare condition that causes low blood sugar)
- if you have kidney or liver disease
- tell all medical doctors, dentists, nurses and pharmacists you go to that you are taking CLOPIDOGREL 75 mg PD.

If you cut or injure yourself, it may take longer than usual for bleeding to stop. This is linked to the way your medicine works as it prevents the ability of blood clots to form. For minor cuts and injuries e.g., cutting yourself shaving, this is usually of no concern. However, if you are concerned by your bleeding, you should contact your doctor straightaway. Your doctor may order blood tests.

Other medicines and CLOPIDOGREL 75 mg PD

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

Please consult your doctor, pharmacist or other healthcare professional for advice if you are using any of the following medicines:

- Non-Steroidal Anti-Inflammatory Agents (such as aspirin, ibuprofen, indomethacin, diclofenac etc.)
- blood clotting medication such as heparin or warfarin

- selective serotonin reuptake inhibitors (medicines that are typically used as antidepressants in the treatment of major depressive disorder, anxiety disorders, and other psychological conditions)
- phenytoin (antiepileptic medicine)
- rifampicin (used to treat severe infections such as tuberculosis (TB)
- tolbutamide and repaglinide (medicine for type-2 diabetes)
- tamoxifen and paclitaxel (medicine used for breast cancer)
- fluvastatin (medicine used to treat high cholesterol)
- omeprazole and esomeprazole (used in the treatment of acid reflux, ulcers)
- fluconazole or voriconazole, medicines to treat fungal infections
- efavirenz or other anti-retroviral medicines (used to treat HIV infections)
- carbamazepine, a medicine to treat some forms of epilepsy
- moclobemide, medicine to treat depression
- opioids: while you are treated with CLOPIDOGREL 75 mg PD, you should inform your doctor before being prescribed any opioid (used to treat severe pain, e.g. morphine).

CLOPIDOGREL 75 mg PD with food and drink

CLOPIDOGREL 75 mg PD tablets may be taken with food or on an empty stomach. CLOPIDOGREL 75 mg PD tablets should be swallowed whole with water, do not chew or crush the tablets (see HOW TO TAKE CLOPIDOGREL 75 mg PD).

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before using CLOPIDOGREL 75 mg PD.

Safety in pregnancy and breastfeeding has not been established.
This medicine should not be taken during pregnancy or breastfeeding (see Do not take CLOPIDOGREL 75 mg PD).

Driving and using machines

CLOPIDOGREL 75 mg PD is not expected to affect your ability to drive or use machines.
It is not always possible to predict to what extent CLOPIDOGREL 75 mg PD 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 CLOPIDOGREL 75 mg PD affects them.

CLOPIDOGREL 75 mg PD contains lactose and hydrogenated castor oil

CLOPIDOGREL 75 mg PD contains lactose. Patients with the rare hereditary conditions of lactose or galactose intolerance should not take CLOPIDOGREL 75 mg PD.
CLOPIDOGREL 75 mg PD contains lactose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

CLOPIDOGREL 75 mg PD contains hydrogenated castor oil which may cause stomach upset or diarrhoea.

3. How to take CLOPIDOGREL 75 mg PD

Do not share medicines prescribed for you with any other person.
Always take/use CLOPIDOGREL 75 mg PD exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The usual dose is one CLOPIDOGREL 75 mg PD tablet daily, with or without food.

CLOPIDOGREL 75 mg PD tablets should be swallowed whole with water. Do not crush or chew the tablets.

Your doctor will tell you how long your treatment with CLOPIDOGREL 75 mg PD will last.
If you have the impression that the effect of CLOPIDOGREL 75 mg PD is too strong or too weak, tell your doctor or pharmacist.

If you take more CLOPIDOGREL 75 mg PD 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 because of the increased risk of bleeding. Take this leaflet and any remaining tablets with you, so that the doctor knows what you have taken.

If you forget to take CLOPIDOGREL 75 mg PD

If you missed a dose, take it as soon as you remember. If it is almost time for your next dose, skip the missed dose and continue to take the tablet at the usual time. Do not take a double or larger dose to make up for the forgotten individual doses.

If you stop taking CLOPIDOGREL 75 mg PD

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

4. Possible side effects

CLOPIDOGREL 75 mg PD can have side effects.

Not all side effects reported for CLOPIDOGREL 75 mg PD are included in this leaflet.

Should your general health worsen, or if you experience any untoward effects while using CLOPIDOGREL 75 mg PD, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop using CLOPIDOGREL 75 mg PD 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
-

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to CLOPIDOGREL 75 mg PD. 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:

- yellowing of the skin and eyes, also called jaundice
- CLOPIDOGREL 75 mg PD may reduce the number of white cells in your blood or general blood count, which may decrease your ability to fight infections. If you experience any infection with symptoms such as fever or a serious deterioration in your general health, or a fever with symptoms such as sore throat/mouth, or bladder problems, you should see your doctor immediately
- unusual bleeding including nose bleeds, bruising or sudden weakness, vomiting of blood or material that looks like ground coffee, black tarry stools and blood in urine or stools, serum sickness with symptoms including joint pain and swollen lymph nodes
- blood disorders which may make you more likely to get infections, get tired very easily, or bruise very frequently
- depression, confusion, hallucinations (hearing, feeling or seeing things that are not there)

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- chest pain, changes in the way your heart beats, for example, if you notice it is beating faster
- serious skin disorders including Stevens-Johnson Syndrome/ toxic epidermal necrolysis (TEN) with flu-like symptoms, followed by a painful red or purplish rash that spreads and blisters, skin sores and peeling of the skin, which could be fatal
- skin rash or skin lesions with a pink/red ring and a pale centre which may be itchy, scaly or filled with fluid. The rash may appear especially on the palms or soles of your feet. These could be signs of a serious skin allergy called ‘erythema multiforme’
- a serious reaction (DRESS) with flu-like symptoms, a widespread rash with a high body temperature and enlarged lymph nodes. Abnormal blood test results may include increased levels of liver enzymes and an increase in a type of white blood cell (eosinophilia)
- hepatitis (symptoms include loss of appetite, nausea or vomiting, unusual tiredness or weakness, yellow eyes or skin), liver failure
- bleeding in the brain (symptoms include increasing headache, vomiting, drowsiness and progressive loss of consciousness, dizziness, confusion, unequal pupil size, slurred speech)
- pancreatitis (inflammation of the pancreas) (symptoms may include upper abdominal pain that radiates into the back; swollen and tender abdomen; nausea and vomiting, fever and increased heart rate)

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- lung diseases like bronchospasm, eosinophilic pneumonia or interstitial pneumonitis (cough, difficulty breathing, noisy breathing, shortness of breath, tightness in chest, wheezing, night sweats, fever)
- serum sickness (a hypersensitivity reaction with symptoms that may include general ill feeling, skin rash, joint stiffness, joint pain, facial and extremity swelling, and fever)
- blood in your urine, foamy or bubbly urine.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- red or purple discoloured spots on the skin, haematoma (a solid swelling of clotted blood within the tissues)
- headache, dizziness
- abdominal or stomach pain, indigestion, diarrhoea
- bruising
- back pain
- fever, chills, or sore throat, difficulty breathing, cough, runny nose or sneezing, nose bleeds
- bleeding at injection site.

Less frequent side effects:

- high blood pressure (severe headaches, vision problems, blurred vision, irregular heart beat)
- bronchitis, shortness of breath
- anxiety, trouble in sleeping, decreased sense of touch or a tingling, numb feeling on the skin
- bleeding in the eye
- bleeding, constipation, vomiting or nausea, stomach ulcer, flatulence, mild abdominal or stomach pain
- dry, itchy and flaky skin
- leg cramps, gout
- bladder infection
- abnormal blood test results.

The following side effects have been reported but the frequency for them to occur is not known:

- an inflammation of the blood vessels that causes changes in the blood vessel walls (vasculitis with symptoms including fever, fatigue, weight loss and muscle and joint pain
- low blood pressure (light-headedness, dizziness, blurred vision, feeling sick, weakness)
- loss of taste, taste disorders, feeling of spinning while being still
- muscle pain, rigidness or stiffness, leg cramps, joint pain and discomfort, arthritis

- frequent, painful or difficult urination, abnormal urine test results
- colitis (inflammation of the bowel with symptoms including diarrhoea, weight loss, abdominal cramping, anemia, and blood or pus in bowel movements)
- inflammation of the mucous membrane of the mouth (causing ulcers, sores, or white spots in mouth)
- enlarged breasts in men
- bleeding in the eye, the lung or the joints
- insulin autoimmune syndrome (condition that causes low blood sugar that manifest in involuntary hunger, tremors, anxiety, irritability, confusion, seizures or loss of consciousness).

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 (who-umc.org) found on SAHPRA website.

By reporting side effects, you can help provide more information on the safety of CLOPIDOGREL 75 mg PD. You can also send an email directly to the company, pharmacovigilance@pharmadynamics.co.za, to ensure safety of the product.

5. How to store CLOPIDOGREL 75 mg PD

Store all medicines out of reach of children.

Store at or below 30 °C

Do not use after the expiry date stated on the 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 CLOPIDOGREL 75 mg PD contains

The active substance is clopidogrel. Each CLOPIDOGREL 75 mg PD tablet contains clopidogrel hydrogen sulphate equivalent to 75 mg of clopidogrel.

The other ingredients are

Anhydrous lactose, castor oil (hydrogenated), hypromellose,

macrogol 6000, microcrystalline cellulose pH102, pregelatinised starch, propylene glycol, purified talc and the colourants iron oxide red and titanium dioxide.

What CLOPIDOGREL 75 mg PD looks like and contents of the pack

Pink, round, biconvex, film coated tablets.

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CLOPIDOGREL 75 mg PD tablets are packed in OPA/AL/PVC film and heat sealing aluminium blister strips. Each strip containing seven or ten tablets. The blister strips are packed in an outer carton in packs of 28 or 30. Not all pack sizes are marketed.

Holder of Certificate of Registration

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