

**PROPOSED PATIENT INFORMATION LEAFLET FOR
PHARMA DYNAMICS CLOPIDOGREL 75 mg**

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

PHARMA DYNAMICS CLOPIDOGREL 75 mg film coated tablet

Read all of this leaflet carefully before you start taking PHARMA DYNAMICS

CLOPIDOGREL 75 mg

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or your pharmacist.
- **PHARMA DYNAMICS CLOPIDOGREL 75 mg** 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.

1. WHAT PHARMA DYNAMICS CLOPIDOGREL 75 mg CONTAINS

The active substance is clopidogrel. Each **PHARMA DYNAMICS CLOPIDOGREL 75 mg** 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 titanium dioxide and iron oxide red.

2. WHAT PHARMA DYNAMICS CLOPIDOGREL 75 mg IS USED FOR

PHARMA DYNAMICS CLOPIDOGREL 75 mg is used to lessen the chance of heart attack

or stroke. It is given to people who have already had a heart attack or stroke or to people with other blood circulation problems that could lead to a stroke or heart attack.

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

3. BEFORE YOU TAKE PHARMA DYNAMICS CLOPIDOGREL 75 mg

Do not take PHARMA DYNAMICS CLOPIDOGREL 75 mg:

- If you are hypersensitive (allergic) to clopidogrel or any of the other ingredients of **PHARMA DYNAMICS CLOPIDOGREL 75 mg** (see **WHAT PHARMA DYNAMICS CLOPIDOGREL 75 mg CONTAINS**).
- If you have bleeding problems (such as bleeding stomach ulcer or increased bleeding tendencies that characterise platelet dysfunction).
- **PHARMA DYNAMICS CLOPIDOGREL 75 mg** 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.

Take special care with PHARMA DYNAMICS CLOPIDOGREL 75 mg:

- If you have thrombotic thrombocytopenic purpura (TTP) – a serious blood disorder.
- If you are going to have surgery or have dental work done. **PHARMA DYNAMICS CLOPIDOGREL 75 mg** 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.

- Tell all medical doctors, dentists, nurses and pharmacists you go to that you are taking **PHARMA DYNAMICS CLOPIDOGREL 75 mg**.

Taking PHARMA DYNAMICS CLOPIDOGREL 75 mg with food or drink:

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

Pregnancy and Breastfeeding:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other health care professional for advice before taking **PHARMA DYNAMICS CLOPIDOGREL 75 mg**.

Safety in pregnancy and breastfeeding has not been established.

Driving and using machinery:

PHARMA DYNAMICS CLOPIDOGREL 75 mg may cause headache or dizziness. You should refrain from driving or using machinery until you know how this medicine affects you.

Important information about some of the ingredients of PHARMA DYNAMICS

CLOPIDOGREL 75 mg:

PHARMA DYNAMICS CLOPIDOGREL 75 mg contains lactose. Patients with the rare hereditary conditions of lactose or galactose intolerance should not take **PHARMA DYNAMICS CLOPIDOGREL 75 mg**.

PHARMA DYNAMICS CLOPIDOGREL 75 mg contains lactose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

Taking other medicines with PHARMA DYNAMICS CLOPIDOGREL 75 mg:

Always tell your healthcare professional 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
- Phenytoin (antiepileptic medicine)
- Tolbutamide (medicine for type-2 diabetes)
- Tamoxifen (medicine used for breast cancer)
- Fluvastatin (medicine used to treat high cholesterol)

4. HOW TO TAKE PHARMA DYNAMICS CLOPIDOGREL 75 mg

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

Always take **PHARMA DYNAMICS CLOPIDOGREL 75 mg** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

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

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

Your doctor will tell you how long your treatment with **PHARMA DYNAMICS CLOPIDOGREL 75 mg** will last.

If you have the impression that the effect of **PHARMA DYNAMICS CLOPIDOGREL 75 mg** is too strong or too weak, tell your doctor or pharmacist.

If you take more PHARMA DYNAMICS CLOPIDOGREL 75 mg than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre. Take this leaflet and any remaining tablets with you, so that the doctor knows what you have taken.

If you forget to take a dose of PHARMA DYNAMICS CLOPIDOGREL 75 mg:

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.

5. POSSIBLE SIDE EFFECTS

PHARMA DYNAMICS CLOPIDOGREL 75 mg can have side effects.

Not all side effects reported for **PHARMA DYNAMICS CLOPIDOGREL 75 mg** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **PHARMA DYNAMICS CLOPIDOGREL 75 mg**, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking **PHARMA DYNAMICS CLOPIDOGREL 75 mg** 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.

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

- **PHARMA DYNAMICS CLOPIDOGREL 75 mg** 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.
- A feeling of sadness accompanied by tiredness, trouble sleeping, appetite changes, irritability and or thoughts of suicide.
- 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 with flu-like symptoms, followed by a painful red or purplish rash that spreads and blisters, skin sores and peeling of the skin.

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

Tell your doctor if you notice any of the following:

- Headache, loss of taste, anxiety, trouble in sleeping, tiredness, confusion, hallucinations (hearing, feeling or seeing things that are not there), decreased sense of touch or a tingling, numb feeling on the skin, dizziness, feeling of spinning while being still.
- Blurred vision, nausea, and feeling pulsations in the neck; cold, pale skin and rapid, shallow breathing.
- Fever, chills, or sore throat; difficulty breathing, cough, runny nose or sneezing.
- Ulcers, sores, or white spots in mouth; diarrhoea or constipation; flatulence; mild abdominal or stomach pain; vomiting or nausea.
- Dry, itchy and flaky skin.
- Joint pain and discomfort, muscle pain, rigidity or stiffness, back pain, leg cramps.
- Frequent, painful or difficult urination.
- Swelling or water retention, body aches and pains, tooth problems.

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

6. STORING AND DISPOSING OF PHARMA DYNAMICS CLOPIDOGREL 75 mg

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

- Store at or below 25 °C.
- Do not use the tablets after the expiry date printed on the label or blister.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

Applicant: Pharma Dynamics (Pty) Ltd

Film-coated tablet, clopidogrel 75 mg

Product Name: **PHARMA DYNAMICS CLOPIDOGREL 75 mg**

Regulation 9 and 10 submitted 30 September 2016- Implemented

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8. IDENTIFICATION OF PHARMA DYNAMICS CLOPIDOGREL 75 mg

Pink, round, biconvex, film coated tablets.