

## **B. PACKAGE LEAFLET**

## **Package leaflet: Information for the user**

### **Plarel 75mg film-coated tablets**

Clopidogrel

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or your pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

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

1. What Plarel is and what it is used for
2. What you need to know before you take Plarel
3. How to take Plarel
4. Possible side effects
5. How to store Plarel
6. Contents of the pack and other information

### **1. What Plarel is and what it is used for**

Plarel contains clopidogrel and belongs to a group of medicines called antiplatelet medicinal products. Platelets are very small structures in the blood which clump together during blood clotting. By preventing this clumping, antiplatelet medicinal products reduce the chances of blood clots forming (a process called thrombosis).

Plarel is taken by adults to prevent blood clots (thrombi) forming in hardened blood vessels (arteries), a process known as atherothrombosis, which can lead to atherothrombotic events (such as stroke, heart attack, or death).

You have been prescribed Plarel to help prevent blood clots and reduce the risk of these severe events because:

- You have a condition of hardening of arteries (also known as atherosclerosis), and
- You have previously experienced a heart attack, stroke or have a condition known as peripheral arterial disease, or
- 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 should also be given acetylsalicylic acid (a substance present in many medicines used to relieve pain and lower fever as well as to prevent blood clotting) by your doctor.

- You have an irregular heartbeat, a condition called ‘atrial fibrillation’, and you cannot take medicines known as ‘oral anticoagulants’ (vitamin K antagonists) which prevent new clots from forming and prevent existing clots from growing. You should have been told that ‘oral anticoagulants’ are more effective than acetylsalicylic acid or the combined use of Plarel and acetylsalicylic acid for this condition. Your doctor should have prescribed Plarel plus acetylsalicylic acid if you cannot take ‘oral anticoagulants’ and you do not have a risk of major bleeding.

## **2. What you need to know before you take Plarel**

### **Do not take Plarel**

- If you are allergic (hypersensitive) to clopidogrel or any of the other ingredients of this medicine (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 think any of these apply to you, or if you are in any doubt at all, consult your doctor before taking Plarel.

### **Warnings and precautions**

If any of the situations mentioned below apply to you, you should tell your doctor before taking Plarel:

- if you have a risk of 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 tissues, 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
- if you have had a clot in an artery of your brain (ischaemic stroke) which occurred within the last seven days
- if you have kidney or liver disease
- if you have had an allergy or reaction to any medicine used to treat your disease.

While you are taking Plarel:

- You should tell your doctor if a surgery (including dental) is planned.
- You should also 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 red pinpoint dots, with or without unexplained extreme

tiredness, confusion, yellowing of the skin or eyes (jaundice) (see section 4 'Possible side effects').

- 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 (see section 4 'Possible side effects').
- Your doctor may order blood tests.

### **Children and adolescents**

Do not give this medicine to children because it does not work.

### **Other medicines and Plarel**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

Some other medicines may influence the use of Plarel or vice versa.

You should specifically tell your doctor if you take

- medicines that may increase your risk of bleeding such as:
  - oral anticoagulants, medicines used to reduce blood clotting,
  - a non-steroidal anti-inflammatory medicine, usually used to treat painful and/or inflammatory conditions of muscle or joints,
  - heparin or any other injectable medicine used to reduce blood clotting,
  - ticlopidine, other antiplatelet agent,
  - a selective serotonin reuptake inhibitor (including but not restricted to fluoxetine or fluvoxamine), medicines usually used to treat depression,
    - omeprazole or esomeprazole, medicines to treat upset stomach,
    - fluconazole or voriconazole, medicines to treat fungal infections,
    - efavirenz, a medicine to treat HIV (human immunodeficiency virus) infections,
    - carbamazepine, a medicine to treat some forms of epilepsy,
    - moclobemide, medicine to treat depression,
    - repaglinide, medicine to treat diabetes,
    - paclitaxel, medicine to treat cancer.

If you have experienced severe chest pain (unstable angina or heart attack), you may be prescribed Plarel in combination with acetylsalicylic acid, a substance present in many medicines used to relieve pain and lower fever. An occasional use of acetylsalicylic acid (no more than 1,000 mg in any 24 hour period) should generally not cause a problem, but prolonged use in other circumstances should be discussed with your doctor.

### **Plarel with food and drink**

Plarel may be taken with or without food.

**Pregnancy and breast-feeding**

It is preferable not to take this product during pregnancy.

If you are pregnant or suspect that you are pregnant, you should tell your doctor or your pharmacist before taking Plarel. If you become pregnant while taking Plarel, consult your doctor immediately as it is recommended not to take clopidogrel while you are pregnant.

You should not breast-feed while taking this medicine.

If you are breast-feeding or planning to breast-feed, talk to your doctor before taking this medicine.

Ask your doctor or pharmacist for advice before taking any medicine.

**Driving and using machines**

Plarel is unlikely to affect your ability to drive or to use machines.

**Plarel contains lactose**

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

**3. How to take Plarel**

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

The recommended dose, including for patients with a condition called 'atrial fibrillation' (an irregular heartbeat), is one 75 mg tablet of Plarel per day to be taken orally with or without food, and at the same time each day.

If you have experienced severe chest pain (unstable angina or heart attack), your doctor may give you 300 mg of Plarel (4 tablets of 75 mg) once at the start of treatment. Then, the recommended dose is one 75 mg tablet of Plarel per day as described above.

You should take Plarel for as long as your doctor continues to prescribe it.

**If you take more Plarel than you should**

Contact your doctor or the nearest hospital emergency department because of the increased risk of bleeding.

**If you forget to take Plarel**

If you forget to take a dose of Plarel, but remember within 12 hours of your usual time, take your tablet straightaway and then take your next tablet at the usual 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 a forgotten tablet.

**If you stop taking Plarel**

**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**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**Contact your doctor immediately if you experience:**

- fever, signs of infection or extreme tiredness. These may be due to rare decrease of some blood cells.
- signs of liver problems such as yellowing of the skin and/or the eyes (jaundice), whether or not associated with bleeding which appears under the skin as red pinpoint dots and/or confusion (see section 2 ‘Warnings and precautions’).
- swelling in the mouth or skin disorders such as rashes and itching, blisters of the skin. These may be the signs of an allergic reaction.

**The most common side effect reported with Plarel is bleeding.**

Bleeding may occur as bleeding in the stomach or bowels, bruising, haematoma (unusual bleeding or bruising under the skin), nose bleed, blood in the urine. In a small number of cases, bleeding in the eye, inside the head, the lung or the joints has also been reported.

**If you experience prolonged bleeding when taking Plarel**

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 (see section 2 ‘Warnings and precautions’).

**Other side effects include:**

Common side effects (may affect up to 1 in 10 people):

Diarrhoea, abdominal pain, indigestion or heartburn.

Uncommon side effects (may affect up to 1 in 100 people):

Headache, stomach ulcer, vomiting, nausea, constipation, excessive gas in stomach or intestines, rashes, itching, dizziness, sensation of tingling and numbness.

Rare side effect (may affect up to 1 in 1,000 people):

Vertigo, enlarged breasts in males.

Very rare side effects (may affect up to 1 in 10,000 people):

Jaundice; severe abdominal pain with or without back pain; fever, breathing difficulties sometimes associated with cough; generalised allergic reactions (for example, overall sensation of heat with sudden general discomfort until fainting); swelling in the mouth; blisters of the skin; skin allergy; sore mouth (stomatitis); decrease in blood pressure; confusion; hallucinations; joint pain; muscular pain; changes in taste of food.

Side effects with frequency not known (frequency cannot be estimated from the available data):  
Hypersensitivity reactions with chest or abdominal pain.

In addition, your doctor may identify changes in your blood or urine test results.

### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via

Pharmaceutical Services  
Ministry of Health  
CY-1475 Nicosia  
Fax: + 357 22608649  
<http://www.moh.gov.cy/phs>

By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Plarel**

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and on the blister after EXP. The expiry date refers to the last day of that month.

In PVC/PE/PVDC/aluminium blisters, store below 25°C.

In PA/ALL/PVC/aluminium blisters, this medicinal product does not require any special storage conditions.

Do not use this medicine if you notice any visible sign of deterioration.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

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

### **What Plarel contains**

- The active substance is clopidogrel. Each film-coated tablet contains 75 mg of clopidogrel (as besilate).

- The other ingredients are:

*Tablet Core:* Cellulose, microcrystalline, hydroxypropylcellulose (E463), mannitol (E421), crospovidone (type A), citric acid monohydrate, macrogol 6000, stearic acid (type 50), talc

*Tablet Coating:* Hypromellose (E464), iron oxide red (E172), lactose monohydrate, triacetin (E1518), titanium dioxide (E171)

### **What Plarel looks like and contents of the pack**

Plarel film-coated tablets are pink, round and biconvex.

They are supplied in PVC/PE/PVDC-Alu blisters or in PA/ALL/PVC-Alu blisters packed in cartons containing 14, 28, 30, 50, 84, 90 or 100 film-coated tablets.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer:**

#### **Marketing Authorisation Holder**

Sapiens Pharmaceuticals Ltd

P.O.Box 56351-3306

Limassol, Cyprus

#### **Manufacturer**

Pharmathen S.A.

Dervenakion Street, Pallini

Attica 15351

Hellas

or

Pharmathen International S.A

Industrial Park Sapes,

Rodopi Prefecture, Block No 5,

Rodopi 69300, Greece

**This medicinal product is authorised in the Member States of the EEA under the following names:**

Germany	Carder 75mg Filmtabletten
Hellas	Carder 75mg film coated tablets
Cyprus	Plarel
Poland	Carder