

**PACKAGE LEAFLET: INFORMATION FOR THE USER**  
**Clopidogrel 75mg film-coated Tablets**  
Clopidogrel (as hydrochloride)

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

- Keep this leaflet. You may need to read it again while you are receiving your treatment.
- If you have any further questions, ask your doctor or 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 have any side effects, including any side effects not listed in this leaflet, talk to your doctor or pharmacist. See section 4.

**What is in this leaflet**

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

**1. What Clopidogrel Tablets are and what they are used for**

Clopidogrel Tablets contain clopidogrel and belong 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).

Clopidogrel Tablets are 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 Clopidogrel Tablets to help prevent blood clots and reduce the risk of these severe events because:

- You have a condition of hardening of the 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 have been 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.

**2. What you need to know before you take Clopidogrel Tablets**

**Do not take Clopidogrel Tablets**

- If you are allergic (hypersensitive) to clopidogrel or any of the other ingredients in 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 Clopidogrel Tablets.

**Warnings and precautions**

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

- 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 Clopidogrel Tablets:**

- 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 Clopidogrel**

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 Clopidogrel Tablets or vice versa.

You should specifically tell your doctor if you take

- 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
- omeprazole, esomeprazole or cimetidine, medicines to treat upset stomach
- fluconazole, voriconazole, ciprofloxacin, or chloramphenicol, medicines used to treat bacterial and fungal infections
- fluoxetine, fluvoxamine, or moclobemide, medicines to treat depression
- carbamazepine, or oxcarbazepine, medicines to treat some forms of epilepsy
- ticlopidine, other antiplatelet agent.

If you have experienced severe chest pain (unstable angina or heart attack), you may be prescribed Clopidogrel Tablets 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 1,000mg in any 24 hour period) should generally not cause a problem, but prolonged use in other circumstances should be discussed with your doctor.

**Clopidogrel Tablets with food and drink**

Clopidogrel Tablets 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 Clopidogrel Tablets. If you become pregnant while taking Clopidogrel Tablets, 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**

Clopidogrel Tablets are unlikely to affect your ability to drive or to use machines.

**Important information about some of the ingredients in Clopidogrel Tablets**

**Clopidogrel Tablets contain hydrogenated castor oil**  
This may cause stomach upsets or diarrhoea.

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### 3. How to take Clopidogrel Tablets

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

If you have experienced severe chest pain (unstable angina or heart attack), your doctor may give you 300mg of Clopidogrel Tablets (one tablet of 300mg or four tablets of 75mg) once at the start of treatment. Then the recommended dose is one 75mg tablet of Clopidogrel per day to be taken orally with or without food, and at the same time each day. You should take Clopidogrel Tablets for as long as your doctor continues to prescribe it.

#### If you take more Clopidogrel Tablets than you should

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

#### If you forget to take Clopidogrel Tablets

If you forget to take a dose of Clopidogrel Tablets, but remember within 12 hours of your usual time, take your tablet straight away 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 Clopidogrel Tablets

**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 Clopidogrel Tablets 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 Clopidogrel Tablets

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 effects (may affect up to 1 in 1000 people):* Vertigo.

*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.

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

If you have any side effects, including any side effects not listed in this leaflet, talk to your doctor or pharmacist.

### 5. How to store Clopidogrel Tablets

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 the month.

This medicine does not require any special storage conditions. Do not use this medicine if you notice any visible signs of deterioration.

Do not throw away any medicine 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 Clopidogrel Tablets contain

The active ingredient is clopidogrel. Each tablet contains 75mg of clopidogrel (as hydrochloride).

The other ingredients are (see section 2 'Clopidogrel Tablets contain hydrogenated castor oil'): macrogol 6000, microcrystalline cellulose, low substituted hydroxypropyl cellulose, glycerol dibehenate, and castor oil hydrogenated in the tablet core and opadry II (containing iron oxide red (E172), macrogol 4000, polyvinyl alcohol, titanium dioxide (E171) and talc) in the tablet coating.

#### What Clopidogrel Tablets look like and the contents of the pack

Clopidogrel Tablets are round, pink tablets with bevelled edges. They are supplied in blister strips in a cardboard outer container in pack sizes of 28, 30, 50 and 84 tablets. Not all pack sizes may be marketed.

#### Marketing Authorisation Holder:

Wockhardt UK Ltd, Ash Road North, Wrexham, LL13 9UF, UK.

#### Manufacturer:

CP Pharmaceuticals Ltd, Ash Road North, Wrexham, LL13 9UF, UK.

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

UK: Clopidogrel 75mg Film-Coated Tablets  
Ireland: Clopidogrel 75mg Film-Coated Tablets  
Germany: Clopidogrel 75mg Filmtabletten  
Poland: Clopidogrel 75mg Tabletki Powlekane  
Cyprus: Clopidogrel 75mg Film-Coated Tablets  
Malta: Clopidogrel 75mg Film-Coated Tablets  
France: Clopidogrel 75mg comprimé pelliculé

#### Other formats:

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge: 0800 198 5000 (UK Only).

Please be ready to give the following information:

Product name	Reference number
Clopidogrel 75mg Tablets	PL 29831/0415

This is a service provided by the Royal National Institute of Blind People.

For the Republic of Ireland please call +353 52 6186000

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