

Clopidogrel 75 mg

film-coated tablets

**SANDOZ****Active substance: clopidogrel bisulphate****Read all of this leaflet carefully before you start taking this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. What Clopidogrel 75 mg is and what it is used for

Clopidogrel belongs to a group of medicines called antiplatelet medicinal products. Platelets are very small structures in the blood, smaller than red or white blood cells, 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 is taken to prevent blood clots (thrombi) forming in hardened blood vessels (arteries), a process known as atherosclerosis, which can lead to atherothrombotic events (such as stroke, heart attack, or death).

You have been prescribed Clopidogrel 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.

2. Before you take Clopidogrel 75 mg**Do not take Clopidogrel**

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

Take special care with Clopidogrel

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

- 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 are taking another type of medicine (see 'Taking other medicines')
- if you have kidney or liver disease

While you are taking Clopidogrel

- 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 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 '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 'Possible side effects').
- Your doctor may order blood tests.
- You should tell your doctor or pharmacist if you notice any side effect not listed in the 'Possible side effects' section of this leaflet or if you notice that a side effect gets serious.

Clopidogrel is not intended for use in children or adolescents.

Taking other medicines

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

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

The use of oral anticoagulants (medicines used to reduce blood clotting) with clopidogrel bisulphate is not recommended.

You should specifically tell your doctor if you take a non-steroidal anti-inflammatory drug, usually used to treat painful and/or inflammatory conditions of muscle or joints, or if you take heparin or any other medicine used to reduce blood clotting, or if you take a proton pump inhibitor (e.g. omeprazole) for upset stomach.

If you have experienced severe chest pain (unstable angina or heart attack), you may be prescribed clopidogrel bisulphate 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 1000 mg in any 24 hour period) should generally not cause a problem, but prolonged use in other circumstances should be discussed with your doctor.

Taking Clopidogrel with food and drink

Food/meals have no influence. Clopidogrel may be taken with or without food.

Pregnancy and breastfeeding

It is preferable not to use this product during pregnancy and breastfeeding. If you are pregnant or suspect that you are pregnant, you should tell your doctor or your pharmacist before taking Clopidogrel. If you become pregnant while taking Clopidogrel, consult your doctor immediately as it is recommended not to take clopidogrel bisulphate while you are pregnant.

While taking Clopidogrel, consult your doctor about the breastfeeding of a baby.

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

Driving and using machines

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

3. How to take Clopidogrel 75 mg

Always take Clopidogrel exactly as your doctor has told you. You should 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 300 mg of clopidogrel bisulphate (1 tablet of 300 mg or 4 tablets of 75 mg) once at the start of treatment. Then, the usual dose is one 75 mg tablet of Clopidogrel per day to be taken orally with or without food, and at the same time each day.

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

If you take more Clopidogrel than you should

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

If you forget to take Clopidogrel

If you forget to take a dose of Clopidogrel, 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 the forgotten individual doses.

If you stop taking Clopidogrel

Do not stop the treatment. Contact your doctor or pharmacist before stopping.

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

4. Possible side effects

Like all medicines, clopidogrel 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 'Take special care with Clopidogrel').
- swelling in the mouth or skin disorders such as rashes and itching, blisters of the skin. These may be signs of an allergic reaction.

The most common side effect (affects 1 to 10 users in 100) reported with Clopidogrel 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

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 'Take special care with Clopidogrel').

Other possible side effects reported with Clopidogrel

Following side-effects are common

(affects 1 to 10 users in 100):

- diarrhoea, abdominal pain, indigestion or heartburn

Following side-effects are uncommon

(affects 1 to 10 users in 1,000):

- headache, dizziness, abnormal touch sensation.
- stomach ulcer, vomiting, nausea, constipation, excessive gas in stomach or intestines
- skin rashes and itching

Following side-effects are rare

(affects 1 to 10 users in 10,000):

- vertigo

Following side-effects are very rare

(affects less than 1 user in 10,000):

- decrease in blood pressure
- taste disorders
- breathing difficulties sometimes associated with cough
- inflammation of the mouth (stomatitis)
- joint pain or muscular pain
- fever
- generalised allergic reactions, swelling in the mouth, blisters of the skin or skin allergy
- jaundice or severe abdominal pain with or without back pain
- confusion or hallucinations

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

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store Clopidogrel 75 mg

Keep out of the reach and sight of children.

Do not use Clopidogrel after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

Blisters: Do not store above 30°C.

Bottles: After first opening (bottle), do not store above 30°C.

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

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information**What Clopidogrel contains**

The active substance is clopidogrel bisulphate.

Each film-coated tablet contains 75 mg of clopidogrel bisulphate (as hydrogen sulphate).

The other ingredients are:

Tablet core:

mannitol (E421); cellulose, microcrystalline; low substituted hydroxypropylcellulose; hydrogenated vegetable oil.

Tablet coating:

hypromellose (E464); titanium dioxide (E171); macrogol 400; iron oxide, red (E172).

Printing Ink:

iron oxide, black (E172); propylene glycol; industrial methylated spirit; isopropyl alcohol; n-butyl alcohol; shellac (partially esterified).

What Clopidogrel looks like and contents of the pack

Clopidogrel 75 mg film-coated tablets are pink colored film coated round shaped tablets with  imprinted on one side and plain on the other side.

Alu/Alu blisters: 14, 28, 30, 50, 56, 60, 84, 90, 98, 100

Actar blisters: 14, 28, 30, 50, 56, 60, 84, 90, 98, 100

HDPE bottle with child-resistant closure: 100

HDPE bottles with ribbed smooth screw closure: 500

Not all pack sizes may be marketed.

Marketing Authorization Holder

Sandoz GmbH

Biochemiestraße 10, 6250 Kundl, Austria

Manufacturer

Lek Pharmaceuticals d.d.

Verovškova 57, 1526 Ljubljana, Slovenia

This leaflet was last approved in July 2009.

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This is a medicament

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instruction of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.

Keep this medicine out of the reach of children.

Council of Arab Health Ministers

Union of Arab Pharmacists