

CLOPI- 75

Clopidogrel bisulphate (75mg)

Consumer Medication Information Leaflet (RiMUP)

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What CLOPI-75 is used for

You have been prescribed Clopi-75 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.

Clopi-75 can help to 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.

How CLOPI-75 works

Clopi-75 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).

Before you use CLOPI-75

When you must not use it

- if you are allergic (hypersensitive) to clopidogrel or any of the other ingredients in Clopi-75;
- 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.

Before you start to use it

Tell your doctor if you:

- plan to have surgery or a dental procedure.
- have a recent serious injury
- have a recent surgery (including dental)
- 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).
- are pregnant or plan to become pregnant. It is not known if Clopidogrel will harm your unborn baby
- are breastfeeding or plan to breastfeed. It is not known if Clopidogrel passes into your breast milk. You and your doctor should decide if you will take Clopidogrel or breastfeed. You should not do both without talking to your doctor.

Taking other medicines

Some other medicines may influence the use of Clopidogrel 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.

➤ Clopidogrel is metabolized to its active form by an enzyme in our body. Concomitant use of medicines that inhibit the activity of that enzyme results in reduced effectiveness of clopidogrel. The medicines that should be avoided using together with clopidogrel include:

- Omeprazole, esomeprazole, cimetidine (medicines used for stomach ulcer or gastritis)
- Fluconazole, ketoconazole, voriconazole (medicines used for fungal infection)
- Fluoxetine, fluvoxamine (antipsychotic medicines)
- The use of oral anticoagulants (such as warfarin, a medicine used to reduce blood clotting) with Clopidogrel is not recommended.
- You should specifically tell your doctor if you take a non-steroidal anti-inflammatory medicinal product, 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.
- An occasional use of acetylsalicylic acid, a substance present in many medicines used to relieve pain and lower fever, should generally not cause a problem, but prolonged use in other circumstances should

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be discussed with your doctor.

How to use CLOPI-75

How much to use

The usual dose is one 75 mg tablet of Clopidogrel per day.

When to use it

You should take CLOPI-75 at the same time each day.

How long to use it

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

If you forget to take it

If you forget to take a dose of Clopidogrel, take your tablet straightaway and then take your next tablet at the usual time.

If it is already near to your next dosing, skip the missing dose and do not take a double dose to make up for a forgotten tablet dose.

If you use too much (overdose)

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

While you are using CLOPI-75

Things you must do

-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).

- 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.

- You should attend all the follow ups given to you and the doctor may order blood tests from time to time.

- You should tell your doctor or pharmacist if you notice any side effect not listed in the see '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.

Things you must not do

- While you are taking clopidogrel, do not take aspirin or other NSAIDs (non-steroidal anti-inflammatory drugs) without your doctor's advice.

- Avoid sports or activities that could result in a bruising or bleeding injury. Use extra caution to avoid cuts when brushing your teeth or shaving.

- Avoid drinking alcohol while taking clopidogrel. Alcohol may increase your risk of bleeding in your stomach or intestines.

Things to be careful of

Do not drive or operate a machine until you know how Clopi-75 affects you.

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.

-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 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.

Other side effects reported are: rashes, itching, jaundice, breathing difficulties sometimes associated with cough; generalised allergic reactions; swelling in the mouth; blisters of the skin; skin allergy; inflammation of the mouth (stomatitis); decrease in blood pressure; confusion; hallucinations; joint pain; muscular pain; taste disorders.

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

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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.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers →Reporting).

Storage and Disposal of CLOPI-75

Storage

Store below 30°C.

Keep medicine out of reach of children.

Disposal

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

Product Description

What it looks like?

Brown coloured, film coated, circular, biconvex tablets having break-line on one side and plain surface on other side.

Ingredients

Active ingredient:

Clopidogrel bisulphate 75mg

Inactive Ingredients:

Povidone, Crospovidone,
Microcrystalline cellulose,
Anhydrous lactose,
Hydrogenated castor oil,
Opadry brown (21S56679),
Dichloromethane, Isopropyl alcohol

MAL NUMBER:

MAL12050007A

Manufacturer

Macleods Pharmaceuticals Ltd.

Plot No. 25-27, Survey No. 366,

Premier Industrial Estate,
Kachigam, Daman -396210 (U.T.)

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Andheri (East), Mumbai - 400 059, INDIA

Product Registration

Holder

Healol Pharmaceuticals Sdn Bhd

74-3, Jalan 1/27F,
KLSC Wangsa Maju, 53300 KL,
Malaysia

Date of revision

06/08/2015

Serial Number

BPFK(R4/1)060815/00235