

CLOPIVAS[®]

Clopidogrel (75 mg)

What is in this leaflet

- 1 What CLOPIVAS is used for
- 2 How CLOPIVAS works
- 3 Before you use CLOPIVAS
- 4 How to use CLOPIVAS
- 5 While you are using it
- 6 Side effects
- 7 Storage and Disposal of CLOPIVAS
- 8 Product Description
- 9 Manufacturer and Product Registration Holder
- 10 Date of Revision

What CLOPIVAS is used for

Clopidogrel is taken to prevent blood clots (thrombosis) from 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 'chest pain' 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.

How CLOPIVAS works

Clopidogrel 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 CLOPIVAS

When you must not use it

Do not take Clopidogrel:

- If you are allergic (hypersensitive) to clopidogrel 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.

- Before you start to use it

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 have kidney or liver disease

- Taking other medicines

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

prescription. Some other medicines may influence the use of Clopidogrel 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 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 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.

Please refer to your doctor or pharmacist for a more detail and complete list of medicines interaction

How to use CLOPIVAS

- How much to use

If you have experienced severe chest pain (unstable angina or heart attack), your doctor may give you 300 mg of Clopidogrel (1 tablet of 300 mg or 4 tablets of 75 mg) once at the start of

CLOPIVAS[®]

Clopidogrel (75 mg)

treatment. Then, the usual dose is one 75-mg tablet of Clopivas per day to be taken orally with or without food, and at the same time each day.

-When to use it

Always take Clopivas exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure

- How long to use it

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

- If you forget to use it

If you forget to take Clopivas:

If you forget to take a dose of Clopivas, take your tablet straightaway and then take your next tablet at the usual time. Do not take a double dose to make up for the forgotten individual doses.

-If you use too much (overdose)

If you take more Clopivas than you should:

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

While you are using it

- 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 (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)

- 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

- Remember to attend all appointments given to you, as your doctor may need to run some blood tests on you

- Clopivas is not intended for use in children or adolescents.

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 Clopivas. If you become pregnant while taking Clopivas, 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.

- Things you must not do

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 product, ask your doctor or pharmacist.

- Things to be careful of

Please do not drive or use machine, until you know how Clopivas affects you

Side effects

Like all medicines, Clopivas 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 reported with Clopivas 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 with Clopivas are:

Common side effects: Bleeding from nose, diarrhoea, abdominal pain, indigestion or heartburn.

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

Rare side effect: Vertigo.

CLOPIVAS[®]

Clopidogrel (75 mg)

Very rare side effects: Jaundice; severe abdominal pain with or without back pain; fever, 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; changes in the way things taste.

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

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 web site: portal.bpfk.gov.my (Consumers → Reporting).

Storage and Disposal of Clopivas

Storage
Store at 25°C

Disposal
Medicines should not be disposed of via waste water 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

Pink coloured circular, biconvex, film coated tablets plain on both sides

- Ingredients

The active ingredient is Clopidogrel bisulfate

-Inactive ingredients:

The other ingredients are Mannitol DC Grade (Pearlitol SD 200), Crospovidone (Kollidon CLM) (CL Micronised), Colloidal Anhydrous silica (Aerosil), Microcrystalline cellulose (Avicel pH 112), Macrogol (Polyethylene glycol 6000 Powder grade), Hydrogenated Castor Oil (Powder grade), Opadry YS-1-14778-A Pink, Purified water

MALNO: MAL10100160A

Manufacturer

Cipla Ltd.
L-139 to L-146
Verna Indl. Estate,
Verna Goa India.

Product Registration Holder

CIPLA MALAYSIA SDN BHD
Suite 1101, Amcorp Tower,
Amcorp Trade Centre,
18 Persiaran Barat,
46 050 Petaling Jaya,
Selangor, Malaysia.

Date of revision

24/07/2015

Serial Number

BPFK(R4/1)200715/00213