

# CLOPRA 75MG FILM-COATED TABLET

Clopidogrel 75mg

---

## What is in this leaflet

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

## What CLOPRA is used for

Clopra is indicated in adults for the prevention of atherothrombotic events (blood clots forming in hardened blood vessels). You are given Clopra because you have:

- Previously suffered from a heart attack, stroke or have a condition known as peripheral arterial disease.
- Previously suffered from a severe type of chest pain known as unstable angina or myocardial infarction/heart attack. Your doctor may have placed a stent in the blocked or narrowed blood vessel to restore blood flow.

You should also be given acetylsalicylic acid (a pain and fever medicine) by your doctor to prevent blood clotting.

## How CLOPRA works

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

Clopra is taken 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).

## Before you use CLOPRA

### When you must not take it

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

### Before you start to take it

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

- Tell your doctor if you have kidney or liver impairment.
- You should not take Clopra if you have hereditary problems of galactose intolerance, the Lapp lactose deficiency or glucose-galactose malabsorption.
- Clopra is not intended for use in children or adolescents.
- You should take special care with Clopra 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 pregnant or suspect that you are pregnant, you should tell your doctor or your pharmacist before taking Clopra. If you become pregnant while taking Clopra, 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.

### 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 Clopra 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,
  - Cimetidine, medicines to treat upset stomach
  - ticlopidine, other antiplatelet agent.
- If you have experienced severe chest pain (unstable angina or heart attack), you may be prescribed.

Clopra 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.

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

## How to use CLOPRA

### How much to take

If you have experienced severe chest pain (unstable angina or heart attack), your doctor may give you 300 mg of Clopra (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 Clopra per day to be taken orally.

# CLOPRA 75MG FILM-COATED TABLET

Clopidrogel 75mg

---

## When to use it

Clopra may be taken with or without food at the same time each day.

## How long to take it

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

## If you forget to take it

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

If you forget to take a dose, Do not take a double dose to make up for the forgotten individual doses.

## If you take too much (overdose)

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

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

## **While you are using CLOPRA**

### Things you must do

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- 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.

### Things you must not do

Do not stop the treatment unless your doctor tells you so. Contact your doctor or pharmacist before stopping. 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.

### Things to be careful of

- You should 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 '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 'Side effects').

### Driving and using machines:

Do not drive or operate machinery until you know how Clopra affects you.

## **Side effects**

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

**Common side effects:** Diarrhoea, abdominal pain, indigestion or heartburn. The most common side effect reported with Clopra 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.

**Uncommon side effects:** Headache, stomach ulcer, vomiting, nausea, constipation, excessive gas in stomach or intestines. Skin disorders such as rashes and itching, blisters of the skin. These may be the signs of an allergic reaction. Itching, dizziness, sensation of tingling and numbness.

**Rare side effect:** Vertigo.

**Very rare side effects:** Jaundice; severe abdominal pain with or without back pain; fever, signs of infection or extreme tiredness. These may be due to rare decrease of some blood cells. 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; angioedema (swelling of the deeper layers of the skin, caused by a build-up of fluid) and anaphylaxis reaction (severe and potentially life-threatening allergic reaction that include airway obstruction).

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

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](http://portal.bpfk.gov.my) (Consumers → Reporting).

## **Storage and Disposal of CLOPRA**

### Storage

Keep out of the reach and sight of children.

Store Clopra in a dry place, below 25°C, in its package.

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

### 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

Pink and round film-coated tablet.

# CLOPRA 75MG FILM-COATED TABLET

Clopidogrel 75mg

---

## Ingredients

Active ingredient:  
Clopidogrel 75 mg.

## Inactive ingredients:

Colloidal silicon dioxide, polyvinyl alcohol, microcrystalline cellulose, polyethylene glycol 3350, titanium dioxide, iron oxide (red), Lactose anhydrous, pregelatinized starch, hydrogenated castor oil, hydroxypropyl cellulose (HPC-L), opadry pink.

## MAL No

MAL11010013A.

## **Manufacturer**

Drogsan Ilacları San. ve Tic. A.S.  
Cubuk, 06760, Ankara, Turkey.

## **Product Registration Holder**

Antah Pharma Sdn. Bhd.  
3, Jalan 19/1, 46300,  
Petaling Jaya, Selangor.

## **Date of Revision**

03 October 2015.

## **Serial number:**

BPFK(R4/1)230715/00221.