

AXCEL CLOPIDOGREL-75MG TABLET

Clopidogrel Bisulphate equivalent to Clopidogrel 75mg

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What Axcel Clopidogrel-75mg Tablet is used for

Axcel Clopidogrel-75mg Tablet is indicated for the prevention of blood clot formation inside blood vessels incidents in:

- Person with history of heart attack, stroke and peripheral arterial disease (leg pain on walking or at rest).
- Person suffering a severe type of chest pain known as unstable angina or heart attack.
- Person with an irregular heartbeat, a condition called 'atrial fibrillation', and not suitable to take medicines known as 'oral anticoagulants' (vitamin K antagonists) which prevent new clots from forming and prevent existing clots from growing.

How Axcel Clopidogrel-75mg Tablet work

Clopidogrel tablets belong to a group of medicines called antiplatelet. 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.

Before you use Axcel Clopidogrel-75mg Tablet

– When you must not use it

Do not take Axcel Clopidogrel-75mg Tablet:

- If you are allergic (hypersensitivity) to clopidogrel or any ingredients in this medicine.
- If you have ulcer in stomach or intestine.
- If you have bleeding within the skull.
- If you have severe liver impairment.

– Before you start to use it

You need to tell your doctor:

- If you have a risk of bleeding such as serious injury, surgery, risk of internal bleeding (such as stomach ulcer), a blood disorder (bleeding inside any tissues, organs or joints of your body).
- If you have severe kidney problems.
- 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.

Pregnancy and lactation

It is preferable not to take this product during pregnancy / breastfeeding. If you are pregnant, or think you might be pregnant, as your doctor for advice before taking this product.

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. You should specifically tell your doctor if you take:

- Anticoagulants, medicines used to reduce blood clotting.

- Glycoprotein IIb/IIIa inhibitors (antiplatelet medicine).
- Acetylsalicylic acid (ASA) (medicine for pain and fever).
- Heparin, thrombolytics (medicines to dissolve blood clots).
- Non-steroidal anti-inflammatory drugs (NSAIDs) (medicine for pain and fever).
- Proton pump inhibitor (e.g. omeprazole or esomeprazole) for upset stomach.
- Fluconazole or voriconazole (medicines to treat fungal infections)
- Efavirenz (medicines used to treat HIV infections)
- Carbamazepine (medicine to treat some forms of epilepsy)
- Repaglinide (medicine to treat diabetes)
- Paclitaxel (medicine to treat cancer)

How to use Axcel Clopidogrel-75mg Tablet

– How much to use

Always take Axcel Clopidogrel-75mg Tablet exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. Ask your doctor or pharmacist if you are unsure of the correct dose for you. They will tell you exactly how much to take.

- The usual dose is one 75mg tablet daily.
- A starting dose for chest pain and heart attack is 300mg and then continued at 75mg once a day.

– When to use it

To be taken orally with or without food, and at the same time each day.

– How long to use it

Use as directed by your doctor or pharmacist.

– If you forget to use it

- Consult your doctor or pharmacist on what you should do if you forget to use it.
- Take the missed dose as soon as you remember. If it is almost time for your next dose, wait

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until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

– If you use too much (overdose)

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

- Take your medicine exactly as your doctor has told you.
- Tell all the doctors, dentists and pharmacists treating you that you are taking Axcel Clopidogrel-75mg Tablet.
- Tell your doctor immediately if you become pregnant while taking this medication.
- 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’).

– Things you must not do

- Do not take any new medicines without consulting your doctor.
- Do not give Axcel Clopidogrel-75mg Tablet to anyone else, even if they have the same symptoms or condition as you.

– Things to be careful of

Driving and using machines Axcel Clopidogrel-75mg Tablet has no or negligible effect on driving and using machines.

Side effects

Like all medicines, Axcel Clopidogrel-75mg Tablet can cause side effects although not everybody gets them. The most common side effect is bleeding. Bleeding may occur as, unusual bleeding or bruising under the skin, nose bleed,

bleeding in the stomach or bowels, blood in the urine or bruising. In a small number of cases, serious bleeding, bleeding of operative wound, bleeding in the eye, inside the head and the lung have been reported. Other side effects reported are:

- Diarrhoea,
- Abdominal pain
- Disordered digestion (dyspepsia)
- Reduced neutrophils count (a type of white blood cells)
- Reduced platelet count (platelet is a blood cell to stop bleeding)
- Nausea (feel like vomiting), gastritis (inflammation of the stomach)
- Headache, dizziness
- Thrombotic thrombocytopenic purpura (TTP) - a rare blood disorder where blood clots form in small vessels throughout the body. This side effect is very rare

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 visiting the website nptra.gov.my [Consumers -> Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and disposal of Axcel Clopidogrel-75mg Tablet

– Storage

Keep Axcel Clopidogrel-75mg Tablet out of reach of children.

Store below 30°C. Protect from light and moisture.

– Disposal

Do not use Axcel Clopidogrel-75mg Tablet after the expiry date which is stated on the carton.

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

Product description

– What it looks like

Pink coloured film-coated, round, biconvex tablet with “75” on one side and Kotra logo on the other side.

– Ingredients

Active Ingredient:

Clopidogrel Bisulphate

Inactive Ingredients:

Microcrystalline cellulose, Polyethylene Glycol, Mannitol, Low Hydroxy Propyl Cellulose, Hydrogenated Castor Oil, Opadry II Pink, Purified Water.

– MAL Number

MAL20106010AZ

Manufacturer and product registration holder

KOTRA PHARMA (M) SDN BHD
No. 1, 2 & 3, Jalan TTC 12,
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