

CLOPIDOGREL STADA[®] FILM-COATED TABLETS

Clopidogrel (75 mg)

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What Clopidogrel Stada[®] is used for

Clopidogrel is indicated for the prevention of blood clot formation inside blood vessels, such as:

- You suffer from heart attack (from a few days until less than 35 days), stroke (from 7 days until less than 6 months) or condition known as artery narrowing disease.
- You have experienced a severe type of chest pain known as unstable angina or 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.

How Clopidogrel Stada[®] works

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 take Clopidogrel Stada[®]

-When you must not take it

- If you are known to have hypersensitivity to clopidogrel or any ingredients in the formulation.
- If you have severe liver impairment.
- If you have a medical condition that is currently causing bleeding such as a peptic ulcer or bleeding within the brain.

If you think any of these apply to you, or if you are in any doubt at all,

consult your doctor before taking this medication.

-Before you start to take it

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

- 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 are pregnant.
- If you are breast-feeding.

-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 receive other medications that:

- increase the risk of bleeding, including medicines used to reduce blood clotting (anticoagulation) and reduce platelet clumping and clotting (antiplatelets) such as heparin and warfarin.
- medicines used to treat painful and/or inflammatory conditions of muscle or joints (Nonsteroidal Anti-inflammatory Drugs) such as aspirin; and medicines used to treat gastritis or stomach problems (proton pump inhibitors).

How to take Clopidogrel Stada[®]

-How much to take

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

The usual dose is one 75-mg tablet of Clopidogrel tablet for adults and elderly patients.

If you have experienced severe chest pain, your doctor may give you 300 mg of Clopidogrel tablet once at the start of treatment, followed by 75 mg daily given (with aspirin 75 mg- 325 mg daily).

-When to take it

Clopidogrel tablets should be taken orally with or without food. You should take your medicine regularly and at the same time each day.

-How long to take it

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

-If you forget to take it

If you forget to take a dose of this medication, 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 take too much (overdose)

It may increase risk of bleeding and prolonged bleeding time. If you have any further questions on the use of this product, ask your doctor or pharmacist.

While you are using Clopidogrel Stada[®]

-Things you must do

- Tell your doctor if a surgery is planned.
- If bleeding or blood disorders are suspected, your doctor may order blood tests.

-Things you must not do

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

-Things to be careful of

- Clopidogrel prolongs bleeding time.
- Use with caution if you have a risk of bleeding.
- Use with caution if you have kidney or liver disease.

Side effects

Like all medicines, Clopidogrel Stada[®] 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, bruising. In a small number of cases, serious bleeding,

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bleeding of operative wound, bleeding in the eye, inside the head and the lung have been reported.

Other side effects reported are:

Common: diarrhoea, abdominal pain, disordered digestion (dyspepsia).

Uncommon: reduction in the number of platelet, white blood cells, headache, abnormal skin sensations, dizziness, ulcer in the stomach and duodenum, inflammation of the lining of the stomach, vomiting, nausea, constipation, flatulence, rash, itching, any intense sensation of itching, skin bleeding, blood in the urine.

Rare: decrease in the number of neutrophils in the blood including severe neutropenia, vertigo and bleeding behind the membrane and wall of the abdominal cavity.

Very rare: a disorder of the blood coagulation system, a disorder in which the bone marrow greatly decreases and stops production of blood cells, a pronounced reduction in number of red blood cells, white blood cells and platelets in the blood, serum sickness, generalised allergic reactions, hallucinations, confusion, taste disturbances, inflammation of the blood vessels, decrease in blood pressure, narrowing of bronchi, severe lung disease, stomach and intestine bleeding with fatal outcome, inflammation of the pancreas, of the colon, of the mouth, of the skin and of the liver, acute liver failure, abnormal liver function test, blisters of the skin, rapid swelling of the skin, skin disorder, skin allergy, skin disease, musculoskeletal bleeding, arthritis, joint pain, muscle pain, kidney disease and fever.

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 npra.moh.gov.my (Public → Reporting

Medicinal Problems / Side Effects / AEFI / Vaccine Safety).

Storage and disposal of Clopidogrel Stada[®]

-Storage

The expiry date of this pack is printed on the box. Do not use this pack after this date. Keep all medicines out of reach of children.

Do not store above 30°C. Store in a dry and cool place.

Do not use Clopidogrel Stada[®] 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

Clopidogrel Stada[®] appears as a pink, round-shaped, biconvex, filmcoated tablet, engraved "75" on one side and plain on the other side.

-Ingredients

Active ingredient: One tablet contains Clopidogrel bisulfate equivalent to 75 mg Clopidogrel.

Inactive ingredients: Lactose monohydrate, microcrystalline cellulose, maize starch, crospovidone, povidone K30, hydrogenated castor oil, colloidal anhydrous silica, hypromellose, macrogol 6000, talc, titanium dioxide, red ferric oxide.

MAL number

MAL12055034AZ

Manufacturer

The manufacturer is STADA-VN J.V. Co., Ltd, (A Joint Venture Company of STADA Arzneimittel AG, Germany), 40 Tu Do Avenue, Vietnam-Singapore Industrial Park, Thuan An, Binh Duong Province, Vietnam.

Product Registration Holder

Stadpharm Sdn. Bhd.
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