

Clopidogrel Bisulphate Tablets USP 75mg Taj Pharma

(Clopidogrel Bisulphate)

Package leaflet: information for the user

Read all of this leaflet carefully before you start taking Clopidogrel Bisulphate because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- Clopidogrel Bisulphate has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Clopidogrel Bisulphate is and what it is used for
2. What you need to know before you take Clopidogrel Bisulphate
3. How to take Clopidogrel Bisulphate
4. Possible side effects
5. How to store Clopidogrel Bisulphate
6. Contents of the pack and other information

1. What Clopidogrel Bisulphate is and what it is used for

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

Clopidogrel Bisulphate is taken by adults 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).

You have been prescribed Clopidogrel Bisulphate 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 ‘unstable angina’ 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 aspirin (a substance present in many medicines used to relieve pain and lower fever as well as to prevent blood clotting) by your doctor.
- You have an irregular heartbeat, a condition called ‘atrial fibrillation’, and you cannot take medicines known as ‘oral anticoagulants’ (vitamin K antagonists) which prevent new clots from forming and prevent existing clots from growing. You should have been told that ‘oral anticoagulants’ are more effective than aspirin or the combined use of Clopidogrel Bisulphate and aspirin for this condition. Your doctor should have prescribed Clopidogrel Bisulphate plus aspirin if you cannot take ‘oral anticoagulants’ and you do not have a risk of major bleeding.

2. What you need to know before you take Clopidogrel Bisulphate

Do not take Clopidogrel Bisulphate

- If you are allergic to Clopidogrel Bisulphate or any of the other ingredients of Clopidogrel Bisulphate (listed in section 6);

- 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 Bisulphate .

Warnings and precautions

If any of the situations mentioned below apply to you, talk to your doctor before taking Clopidogrel Bisulphate :

- 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
 - recent surgery (including dental procedures)
 - planned surgery (including dental procedures). You will need to stop taking Clopidogrel Bisulphate seven days before any planned surgery
- 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
- if you have had an allergy or reaction to any medicines used to treat your disease.

While you are taking Clopidogrel Bisulphate:

- You should tell your doctor if you are to have surgery (including dental procedures).
- 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) (see section 4 ‘Possible 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 4 ‘Possible side effects’).
- Your doctor may order blood tests.

Children and Adolescents

Do not give Clopidogrel Bisulphate to children because it does not work.

Other medicines and Clopidogrel Bisulphate

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. Some other medicines may influence the use of Clopidogrel Bisulphate or vice versa.

You should specifically tell your doctor if you take:

- medicines that may increase your risk of bleeding such as:
 - oral anticoagulants, medicines used to reduce blood clotting,
 - a non-steroidal anti-inflammatory medicine, usually used to treat painful and/or inflammatory conditions of muscles or joints,
 - heparin or any other injectable medicine used to reduce blood clotting,
 - ticlopidine, another antiplatelet agent,
 - a selective serotonin reuptake inhibitor (including but not restricted to fluoxetine or fluvoxamine), medicines usually used to treat depression,

- omeprazole or esomeprazole, medicines to reduce excess stomach acid,
- fluconazole or voriconazole, medicines to treat fungal infections,
- efavirenz, a medicine to treat HIV (human immunodeficiency virus) infections,
- moclobemide, medicine to treat depression
- carbamazepine a medicine used to treat some forms of epilepsy,
- repaglinide, medicine to treat diabetes,
- paclitaxel, medicine to treat cancer,
- anti-retroviral medicines (medicines to treat HIV infections).

If you have experienced severe chest pain (unstable angina or heart attack), you may be prescribed Clopidogrel Bisulphate in combination with aspirin, a substance present in many medicines used to relieve pain and lower fever. An occasional use of aspirin (no more than 1,000mg in any 24 hour period) should generally not cause a problem, but prolonged use in other circumstances should be discussed with your doctor.

Clopidogrel Bisulphate with food and drink

Clopidogrel Bisulphate may be taken with or without food.

Pregnancy and breast-feeding

It is preferable not to take Clopidogrel Bisulphate during pregnancy.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking Clopidogrel Bisulphate . If you become pregnant while taking Clopidogrel Bisulphate , consult your doctor immediately as it is recommended not to take Clopidogrel Bisulphate while you are pregnant.

You should not breast-feed while taking Clopidogrel Bisulphate .

If you are breast-feeding or planning to breast-feed, talk to your doctor before taking Clopidogrel Bisulphate .

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

Driving and using machines

Clopidogrel Bisulphate is unlikely to affect your ability to drive or to use machines.

Clopidogrel Bisulphate contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Clopidogrel Bisulphate .

3. How to take Clopidogrel Bisulphate

Always take Clopidogrel Bisulphate exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose, including for patients with a condition called 'atrial fibrillation' (an irregular heartbeat), is one 75mg tablet of Clopidogrel Bisulphate per day to be taken orally with or without food, and at the same time each day.

If you have experienced severe chest pain (unstable angina or heart attack), your doctor may give you 300mg of Clopidogrel Bisulphate (4 tablets of 75mg) once at the start of treatment. Then, the recommended dose for adults, including the elderly, is one 75mg tablet of Clopidogrel Bisulphate per day as described above.

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

If you take more Clopidogrel Bisulphate than you should

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

If you forget to take Clopidogrel Bisulphate

If you forget to take a dose of Clopidogrel Bisulphate , but remember within 12 hours of your usual time, take your tablet straightaway and then take your next tablet at the usual time.

If you forget for more than 12 hours, simply take the next single dose at the usual time. Do not take a double dose to make up for a forgotten tablet.

If you stop taking Clopidogrel Bisulphate

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 Clopidogrel Bisulphate, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Clopidogrel Bisulphate 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 (see section 2 'Warnings and precautions').
- 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 Clopidogrel Bisulphate 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.

If you experience prolonged bleeding when taking Clopidogrel Bisulphate

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 2 'Warnings and precautions').

Other side effects may include:

- Common side effects (may affect up to 1 in 10 people): Diarrhoea, abdominal pain, indigestion or heartburn.
- Uncommon side effects (may affect up to 1 in 100 people): Headache, stomach ulcer, vomiting, nausea, constipation, excessive gas in stomach or intestines, rashes, itching, dizziness, sensation of tingling and numbness.
- Rare side effects (may affect up to 1 in 1000 people): Vertigo, enlarged breasts in males.
- Very rare side effects (may affect up to 1 in 10,000 people): Jaundice; severe abdominal pain with or without back pain; fever; breathing difficulties sometimes associated with cough; generalised allergic reactions (for example, overall sensation of heat with sudden general discomfort until fainting); swelling in the mouth; blisters of the skin; skin allergy; sore mouth (stomatitis); decrease in blood pressure; confusion; hallucinations; joint pain; muscular pain; changes or loss of the taste of food.
- Side effects with frequency not known (frequency cannot be estimated from the available data): Hypersensitivity reactions with chest or abdominal pain, persistent low blood sugar symptoms.

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

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

5. How to store Clopidogrel Bisulphate

Keep Clopidogrel Bisulphate out of the sight and reach of children.

Do not use Clopidogrel Bisulphate after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

Store below 25°C.

Do not use Clopidogrel Bisulphate if you notice any visible signs of deterioration.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Clopidogrel Bisulphate contains

The active substance is Clopidogrel Bisulphate .

Each film coated tablet contains:

Clopidogrel bisulphate USP

Equivalent to Clopidogrel 75mg

Clours: Red oxide of Iron, Titanium Dioxide
USP

The other ingredients are:

Tablet core: Microcrystalline cellulose, Mannitol , Hydroxypropylcellulose, Crospovidone, Citric acid monohydrate, Macrogol , Stearic acid, Talc.

Tablet coating: Hypromellose, Lactose monohydrate, Iron oxide red, Triacetin, Titanium dioxide.

What Clopidogrel Bisulphate looks like and contents of the pack

Clopidogrel Bisulphate film-coated tablets are round and biconvex. They are supplied in PVC/PE/PVDC/Aluminium blisters or in

PA/ALL/PVC - Aluminium foil (Alu-Alu) blisters.

Packs Available: 14, 28, 30, 50, 56, 84, 90, 98, 100 and 500 film-coated tablets

Not all pack sizes may be marketed.

7. MANUFACTURED IN INDIA BY: TAJ PHARMACEUTICALS LTD.

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