

KOGREL® FILM COATED TABLET

Clopidogrel bisulphate (75mg)

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1. What Kogrel is used for

You have been prescribed Kogrel 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.

2. How Kogrel works

Clopidogrel belongs to a group of medicines called antiplatelet medicinal products. 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 (a process called thrombosis).

Clopidogrel is taken to prevent blood clots forming in hardened blood vessels (arteries), a process known as atherothrombosis, which can lead to atherothrombotic events (such as stroke, heart attack, or death).

3. Before you take Kogrel

- When you must not use it

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

- Before you start to use it

Tell your doctor or pharmacist before starting to take KOGREL if you have or have had:

- 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 medicine. This includes medicines that your doctor has not prescribed for you but which you have bought yourself from a pharmacist. 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 medicine used to reduce blood clotting,
- a proton pump inhibitor (e.g. omeprazole) for upset stomach,
- cimetidine, medicine to treat upset stomach

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 1000 mg in any 24 hour period) should generally not cause a problem, but prolonged use in other circumstances should be discussed with your doctor.

Pregnancy and breast-feeding

Kogrel should not be used while breastfeeding/pregnant. If you are pregnant, or think you might be pregnant, ask your doctor for advice before taking any medicine.

4. How to take Kogrel

- How much to use

- Always take Kogrel exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure
- If you have experienced severe chest pain (unstable angina or heart attack), your doctor may give you 300 mg of Kogrel (4

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

- When to use it

Taking Kogrel with food and drink

Kogrel may be taken with or without food

- How long to use it

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

- If you forget to use it

If you forget to take a dose of Kogrel, 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)

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

5. 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.

- Things you must not do

KOGREL is not intended for use in children or adolescents.

- Things to be careful of

Driving and using machines

Clopidogrel has no or negligible effect on driving and using machines.

Do not drive or operate machine until you know how Kogrel affect you.

6. Side effects

Like all medicines, Kogrel 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 signs of an allergic reaction.

The most common side effect (affects 1 to 10 users in 100) **reported with Kogrel 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 possible side effects reported with clopidogrel

Common side-effects (affects 1 to 10 patients in 100):

- diarrhoea, abdominal pain, indigestion or heartburn

Uncommon side-effects (affects 1 to 10 patients in 1,000):

- headache, dizziness, sensation of tingling and numbness
- stomach ulcer, vomiting, nausea, constipation, excessive gas in stomach or intestines
- rashes and itching

Rare side-effect (affects 1 to 10 patients in 10,000):

- vertigo

Very rare side-effects (affects less than 1 patient in 10,000):

- decrease in blood pressure
- changes in the way things taste
- breathing difficulties sometimes associated with cough
- inflammation of the mouth (stomatitis)
- joint pain or muscular pain
- fever
- generalised allergic reactions, swelling in the mouth, blisters of the skin or skin allergy
- jaundice or severe abdominal pain with or without back pain
- confusion or hallucinations

In addition, your doctor may identify changes in your blood or urine tests. 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 portal.bpfk.gov.my (Consumers → Reporting).

7. Storage and Disposal of Kogrel

- Storage

Keep out of the reach and sight of children.

Do not use Kogrel after the expiry date. The expiry date refers to the last day of that month.

Do not store above 25°C.

Do not use Kogrel 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.

8. Product Description

- What it looks like

Description: pink colored film coated round shaped tablets engraved with 'SZ' 75 on one side and plain on the other side.

- Ingredients

- Active ingredient(s)

The active substance is clopidogrel.

Each film-coated tablet contains 75mg of clopidogrel (as bisulphate).

- Inactive ingredients

-Tablet Core:

- Mannitol (E421)
- Cellulose, microcrystalline
- Low substituted hydroxypropylcellulose
- Hydrogenated vegetable oil

-Coating:

- Opadry Pink 03B54942
- Purified Water

- MAL number:

MAL09122044A

Manufacturer

Sandoz Private Limited (SPL)

MIDC,

Plot no. 8 A/2 & 8-B

TTC Ind. Area, Kalwe Block

Village Dighe, Navi

Mumbai – 400 708

India

Product Registration Holder

Novartis Corporation (M) Sdn. Bhd.

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