

Clopidogrel bisulphate (75mg)

What is in this leaflet

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

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.
- You have given acetylsalicylic acid (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 experienced symptoms of a stroke which go away within a short period of time (also known as transient ischemic attack) or an ischemic stroke mild in severity. You may also be given acetylsalicylic acid by your doctor starting within the first 24 hours.
- 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 acetylsalicylic acid or the

combined use of Plavix and acetylsalicylic acid for this condition. Your doctor should have prescribed Plavix plus acetylsalicylic acid if you cannot take 'oral anticoagulants' and you do not have a risk of major bleeding.

How *Kogrel* works

Kogrel 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).

Kogrel 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 take *Kogrel***- When you must not use it**

- If you are allergic (hypersensitive) to *Kogrel* 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 (ischemic 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 medicine used to treat your disease.
- if you had a past medical history of non-traumatic brain hemorrhage.

Pregnancy and lactation

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.

- 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 *Kogrel* 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,
- ticlopidine, other antiplatelet agent,
- a selective serotonin reuptake inhibitor (including but not restricted to fluoxetine or fluvoxamine), medicines to treat depression,
- rifampicin (used to treat severe infections),
- omeprazole or esomeprazole, medicines to treat upset stomach,
- fluconazole or voriconazole, medicines to treat fungal infections,
- efavirenz, or other anti-retroviral medicines (used to treat HIV infections),

- carbamazepine, a medicine to treat some forms of epilepsy,
- moclobemide, medicine to treat depression,
- repaglinide, medicine to treat diabetes,
- paclitaxel, medicine to treat cancer,
- opioids: while you are treated with clopidogrel, you should inform your doctor before being prescribed any opioid (used to treat severe pain).
- rosuvastatin (used to lower your cholesterol level).
- If you have experienced severe chest pain (unstable angina or heart attack), you may be prescribed *Kogrel* 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

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 or 600mg of *Kogrel* (4 – 8 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.
 - If you have experienced symptoms of a stroke which go away within a short period of time (also known as transient ischemic attack) or an ischemic stroke mild in severity, your doctor may give you 300 mg of *Kogrel* (4 tablets of 75 mg) once at the start of treatment. Then, the recommended dose is one 75 mg tablet of *Kogrel* per day as described above with acetylsalicylic acid for 3 weeks. Then the physician would prescribe either *Kogrel* alone or acetylsalicylic acid alone.
- When to use it

Always use this medicine exactly as your doctor told you. Please ask your doctor or pharmacist if you are not sure. *Kogrel* may be taken with or without food, and at the same time each day.

- 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

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 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 immediately or go to the nearest emergency department if you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

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

- Do not stop taking the medicine unless advised by your doctor.
- Do not take any new medicines without consulting your doctor.
- Do not give this medicine to anyone else, even if they have the same symptoms or condition as you.
- This medicine is not intended for use in children or adolescents.

- Things to be careful of

Driving and using machines

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

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

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 common side effect 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 (uncommon side effects), bleeding in the eye, inside the head, the lung or the joints has also been reported.

Other common side effects:

- diarrhoea, abdominal pain, indigestion or heartburn

Uncommon side effects:

- abnormalities in blood levels
- headache, dizziness, sensation of tingling and numbness

- stomach ulcer, vomiting, nausea, constipation, excessive gas in stomach or intestines
- rashes and itching

Rare side effects:

- low levels of neutrophils
- vertigo
- enlargement of a man's breast

Very rare side effects:

- 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

Frequency not known:

- hypersensitivity reactions with chest or abdominal pain
- persistent low blood sugar symptoms

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 visiting the website nptra.gov.my (Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

Storage and Disposal of Kogrel

- Storage

Keep out of the reach and sight of children.

Do not use *Kogrel* after the expiry date.

Do not store above 30°C.

- 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 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 75 mg of clopidogrel (as bisulphate).

Inactive ingredients

Tablet Core

Mannitol
Cellulose, microcrystalline
Hydroxypropyl Cellulose
Hydrogenated vegetable oil

Coating

Opadry Pink
Purified Water

Overprinting

Opacode

- MAL number

MAL09122044AZ

Manufacturer

Sandoz Private Limited
Plot no. 8 A/2 & 8-B
TTC Ind. Area, Kalwe Block
Village Dighe,
Navi Mumbai
400 708, India

Product Registration Holder

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