





#### Package leaflet: Information for the user

### Clogrel 75 mg

#### Clogrel film-coated tablets Clopidogrel

Read all of this leaflet carefully before you start taking this medicine 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 your pharmacist.
- This medicine 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 Clogrel is and what it is used for
2. What you need to know before you take Clogrel
3. How to take Clogrel
4. Possible side effects
5. How to store Clogrel
6. Contents of the pack and other information

#### 1. What Clogrel is and what it is used for

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

Clogrel 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 Clogrel 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 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 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 Clogrel and acetylsalicylic acid for this condition. Your doctor should have prescribed Clogrel plus acetylsalicylic acid 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 Clogrel

##### Do not take Clogrel

If you are allergic (hypersensitive) to clopidogrel, soya oil, peanut oil or any of the other ingredients of this medicine (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 Clogrel.

##### Warnings and precautions

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

- 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.
- if you have had an allergy or reaction to any medicine used to treat your disease.

##### While you are taking Clogrel:

- 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) (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

Clogrel is not intended for use in children or adolescents.

Other medicines and Clogrel

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 Clogrel 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 injectable medicine used to reduce blood clotting,
- omeprazole, esomeprazole or cimetidine, medicines to treat upset stomach,
- fluconazole, voriconazole, ciprofloxacin, or chloramphenicol, medicines to treat bacterial and fungal infections,
- fluoxetine, fluvoxamine, or moclobemide, medicines to treat depression,
- carbamazepine, or oxcarbazepine, medicines to treat some forms of epilepsy,
- ticlopidine, other antiplatelet agent.

If you have experienced severe chest pain (unstable angina or heart attack), you may be prescribed Clogrel 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 1,000 mg in any 24 hour period) should generally not cause a problem, but prolonged use in other circumstances should be discussed with your doctor.

##### Clogrel with food and drink

Clogrel may be taken with or without food.

##### Pregnancy and breast-feeding

It is preferable not to take this product during pregnancy.

If you are pregnant or suspect that you are pregnant, you should tell your doctor or your pharmacist before taking Clogrel. If you become pregnant while taking Clogrel, consult your doctor immediately as it is recommended not to take clopidogrel while you are pregnant.

You should not breastfeed while taking this medicine.

- If you are breastfeeding or planning to breastfeed, talk to your doctor before taking this medicine.
- 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 this medicine.

##### Driving and using machines:

Clogrel is unlikely to affect your ability to drive or to use machines.

##### Important information about some of the ingredients of Clogrel

Clogrel contains lactose. If you have been told by your doctor that you have intolerance to some sugars (e.g. lactose), contact your doctor before

taking this medicine.

Clogrel contains soya oil. If you are allergic to peanut or soya, do not take this medicine.

#### 3. How to take Clogrel

Always take this medicine 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 clopidogrel (1 tablet of 300 mg or 4 tablets of 75 mg) once at the start of treatment. Then, the usual dose is one 75 mg tablet of Clogrel per day to be taken orally with or without food, and at the same time each day.

##### You should take Clogrel for as long as your doctor continues to prescribe it.

If you take more Clogrel than you should

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

If you forget to take Clogrel

- If you forget to take a dose of Clogrel, 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 the forgotten tablet.

##### If you stop taking Clogrel

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 this medicine, ask your doctor or pharmacist.

#### 4. POSSIBLE SIDE EFFECTS

Like all medicines, Clogrel 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 Clogrel 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 Clogrel

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 reported with Clogrel are: 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 effect (may affect up to 1 in 1000 people): Vertigo.

##### 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 in taste of food.

##### Immune system disorders:

Insulin autoimmune syndrome, which can lead to severe hypoglycemia,

particularly in patients with HLA DRA4 subtype (more frequent in the Japanese population)\*

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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in leaflet below. By reporting side effects you can help provide more information on the safety of this medicine.

#### 5. How to store Clogrel

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the pack, Do not store above 30°C.

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 Clogrel contains

The active substance is clopidogrel as hydrogen sulphate. Each film-coated tablet contains 75 mg of clopidogrel.

The other ingredients are:

- Tablet core: lactose anhydrous, microcrystalline cellulose, crospovidone Type A, glycerol dibehenate, talc.
- Tablet coating: polyvinyl alcohol, talc, macrogol 3350, lecithin (soya oil) (E322), titanium dioxide (E171), iron oxide red (E172).

##### What Clogrel looks like and contents of the pack

Film-coated tablet.

Pink 9 mm round, biconvex, film-coated tablet, engraved with "A1" on one face.

##### Pack sizes:

Packed in Alu-Alu blister; 30 tablets.

##### Marketing Authorization Holder

AJA Pharmaceutical Industries Company, Ltd.  
Saudi Arabia, Riyadh  
The Business Gate, Cordoba  
G Floor, Zone C2,

##### Manufacturer

AJA Pharmaceutical Industries Company, Ltd.  
Hail Industrial City MODON, Street No 32  
PO Box 6979, Hail 55414  
Kingdom of Saudi Arabia

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##### To report any side effect(s):

- **Saudi Arabia:**
  - The National Pharmacovigilance and Drug Safety Centre (NPC)
  - Fax: +966-11-205-7662
  - Call NPC at +966-11-2038222, Exts: 2317-2334-2354-2353-2356-2340.
  - Toll free phone: 8002490000
  - E-mail: npc.drug@sfdia.gov.sa
  - Website: www.sfdia.gov.sa/npc

##### Other GCC States:

Please contact the relevant competent authority.

##### This is a Medicament

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

Council of Arab Health Ministers  
Union of Arab Pharmacists

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