



AGGRIX®

(Clopidogrel Bisulphate)

Properties:

Aggrix® (clopidogrel bisulphate) belongs to a group of medicines called antiplatelet medicinal products. Platelets are very small structures, 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).

Indications:

Aggrix® is taken to prevent blood clots forming in hardened blood vessels and to reduce the risk of atherothrombotic events (such as stroke, heart attack, or death) in the following cases:

- Condition of hardening of arteries (known as atherosclerosis).
- Previously experienced heart attack, stroke or having a condition known as peripheral arterial disease, or
- Experiencing a severe type of chest pain known as "unstable angina" or "myocardial infarction" (heart attack). In this case the patient may also be given acetylsalicylic acid by his/her doctor.

Side Effects:

Occasional side-effects reported with clopidogrel are:

- Skin disorders such as: rashes and/or itching.
- Gastrointestinal disorders such as: abdominal pain, diarrhea, constipation, indigestion or heartburn, nausea, and vomiting.
- Central nervous system disorders such as: headache, dizziness, confusion, and hallucinations.
- Tingling sensation in hands and feet.
- Bleeding disorders: nose bleeds, bleeding in the stomach or bowels.
- Bruising.
- Blood in the urine.
- Hepatic and biliary disorders.
- Taste disorders.
- Generalized allergic reactions such as: swelling of the face, lips and/or tongue, shortness of breath, fever and articular pain.

In very rare cases, decrease of white blood cells has been reported. Bleeding from blood vessels such as in the eye, lung, muscle, joint and inside the head has been reported in a small number of cases. If clopidogrel is taken with acetylsalicylic acid, non-steroidal anti-inflammatory drugs, heparin and other drugs which could cause or prolong bleeding, or if the patient is at risk of bleeding from trauma, surgery or other pathological conditions, he/she should tell the doctor or the pharmacist about any bleeding he/she may experience.

Contraindications:

Clopidogrel is contraindicated in the following cases:

- Known allergic reaction to any of the components.
- Medical condition that causes bleeding such as a stomach ulcer.
- Severe liver disease.
- Breast-feeding.

Precautions:

The doctor should be informed if the patient has one of the following cases:

- Recent serious injury.
- Recently undergone surgery (including dental).
- Blood disorder that might lead to internal bleeding.
- Medical condition that increases the risk of internal bleeding (such as a stomach ulcer).
- Having surgery (including dental) in the next two weeks.
- Kidney or liver disease.
- Taking another type of medication. This includes all medications, even those purchased without a medical prescription.

In case of prolonged bleeding when taking clopidogrel:

In case of any cut or injury, it may take slightly longer than usual for bleeding to stop. This is linked to the way the medicine works. For minor cuts and injuries e.g. shaving cuts, this is of no concern. However, if any doubts are found, the patient should contact the doctor straightaway.

Drivers and Machine Operators:

The ability to drive or to operate complicated machinery should not be affected by clopidogrel.

Pregnancy and Lactation:

Pregnancy category (B).

In these cases the doctor should be informed before taking clopidogrel.

Drug-Drug Interactions:

- **Acetylsalicylic acid:** patients who have experienced severe chest pain (unstable angina or heart attack) may be prescribed clopidogrel in combination with acetylsalicylic acid (75-325 mg/day). A fixed daily dose of 75-100 mg of acetylsalicylic acid is usually recommended for long-term co-administration with clopidogrel in these patients. In other circumstances, the use of acetylsalicylic acid for prolonged periods needs to be discussed with the doctor. An occasional use of acetylsalicylic acid (no more than 1000 mg in any 24 hour period) should not cause a problem.
- **Other medicinal products used to reduce blood clotting** such as warfarin and heparin are not recommended to be taken with clopidogrel.
- **Non-Steroidal Anti-Inflammatory medicinal products** when taken for prolonged periods are not recommended to be taken with clopidogrel.
- **Some other medicines**, whether prescribed by the doctor or bought over the pharmacy counter, may interact with the actions of clopidogrel to have unwanted effects. If any doubts are found regarding taking another medicine while taking clopidogrel, the patient should see the doctor or the pharmacist.

Overdosage:

In case of overdose, the patient should inform the doctor at once or go to the nearest hospital emergency department. A large dose of tablets could put the patient at risk of serious bleeding, requiring emergency treatment.

Dosage and Administration:

Aggrix® is taken orally.

Adults (including the elderly): one tablet daily with or without food, to be taken regularly and at the same time each day. **Aggrix®** could be taken as 4 tablets of 75 mg (300mg) at start of the treatment for severe chest pain (unstable angina or heart attack).

Children and Adolescents: **Aggrix®** is not intended for children or adolescents below the age of 18 years.

Management in the event of omission of one or several doses:

If one dose of **Aggrix®** is missed, and then being remembered within 12 hours of the usual time, then the patient should take the tablet straightaway and then the next tablet at the normal time. If the tablet is being remembered after 12 hours of its usual time, then the patient should take the next single dose at the usual time. The patient should not double the dose to make up for the missed one.

Presentations:

Aggrix® 75 tablets: each tablet contains 75 mg clopidogrel as clopidogrel bisulphate in a pack of 28 tablets.

Hospital packs are available.

Storage Conditions:

Store in a dry place up to 30°C.

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, method of use and the instructions of pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the prescription without consulting your doctor.
- Keep out of reach of children.

Manufactured by: Middle East Pharmaceutical Company – MIDPHARMA – Jordan.

PI 047

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Rev. 06/06