

CLOPIDOGREL ACTAVIS FILM-COATED TABLETS

Clopidogrel bisulphate 75mg

What is in this leaflet

1. What Clopidogrel Actavis is used for
2. How Clopidogrel Actavis works
3. Before you use Clopidogrel Actavis
4. How to use Clopidogrel Actavis
5. While you are using it
6. Side effects
7. Storage and Disposal of Clopidogrel Actavis
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

What Clopidogrel Actavis is used for

Clopidogrel Actavis is indicated for prevention of thrombotic (blood clotting) incidents in:

- Person with history of heart attack, stroke and peripheral arterial disease (leg pain on walking or at rest).
- Person suffering chest pain (unstable angina), in combination with acetylsalicylic acid (for example, aspirin).

How Clopidogrel Actavis works

Clopidogrel Actavis is a medicinal product which inhibits aggregation (adhesion) of platelets in blood vessels and thus preventing the blood platelets to clump together to reduce the danger from development of blood clots.

Before you use Clopidogrel Actavis

- When you must not use it
Do not use Clopidogrel Actavis if you have or if you are:
 - Allergy to the active substance or any of the other ingredients;
 - Active bleeding (like in gastric ulcer or bleeding in the brain);
 - Liver disease or damage;
 - Pregnant and breast-feeding;
 - Children.
- Before you start to use it
Consult your doctor or pharmacist before taking Clopidogrel Actavis if:
 - You have trauma, operation or internal bleeding (especially in the stomach and the eye) before this.

- You are taking acetylsalicylic acid (Aspirin), nonsteroidal anti-inflammatory medicines (NSAIDs), heparin, glycoprotein IIb/IIIa inhibitors or thrombolytics. As they can increase your risk of bleeding if taken together with Clopidogrel Actavis.
- You have planned for any operation and the blood thinning effect is not desirable. Your doctor may ask you to discontinue the treatment with Clopidogrel Actavis 5 days prior to operation.
- You will be undergoing dental surgery and before starting the treatment with new medicinal product.

- Taking other medicines

Clopidogrel Actavis may interact with the following medicines:

- Warfarin (blood thinning medicine)
- Glycoprotein IIb/IIIa inhibitors (antiplatelet medicine)
- Acetylsalicylic acid (ASA) (medicine for pain and fever)
- Heparin, thrombolytics (medicines to dissolve blood clots)
- Non-steroidal anti-inflammatory drugs (NSAIDs) (medicine for pain and fever)
- Phenytoin (anti-epileptic medicine)
- Tolbutamide (medicine for type 2 diabetes)
- Tamoxifen (breast cancer medicine)
- Torsemide (high blood pressure medicine)
- Fluvastatin (high cholesterol medicine)

How to use Clopidogrel Actavis

- How much to use

You should take a single daily dose of Clopidogrel Actavis 75mg by mouth, with food or without food. If you have had unstable angina or heart attack, treatment should be started with a single 300mg loading dose and continued at 75mg once a day.

Children and adolescents:

Clopidogrel Actavis is not recommended for person below the age of 18.

- When to use it

Clopidogrel Actavis should be taken at the same time every day.

- How long to use it

You should take your medicine for long term under supervision of your doctor.

- If you forget to use it

If you forget to take a dose, take it as soon as you remember. If it is nearly time for your next scheduled dose, you may skip the forgotten dose and take the next dose at the right time. Do not take a double dose to make up for a forgotten dose.

- If you use too much (overdose)

Overdose in treatment with clopidogrel may provoke prolongation of bleeding time, which may lead to bleeding complications. If you have accidentally taken more than your prescribed dose, please contact your nearest doctor or pharmacist immediately together with the pack and any remaining tablets.

While you are using it

- Things you must do

You should inform another doctor or dentist that you are on clopidogrel treatment if you should see them.

- Things you must not do

Pregnancy and breast-feeding

Clopidogrel Actavis should not be administered during pregnancy or lactation. If its application is imperative, you should discontinue breast-feeding.

- Things to be careful of

Driving and operating machine

It is not established Clopidogrel Actavis to affect unfavourably the ability to drive and use machine.

Side effects

- Bleeding symptoms in the stomach, bowels or the eyes
- Nose bleeding

- Blood in urine
- Reduced neutrophils count (a type of white blood cells)
- Reduced platelet count (platelet is a blood cell to stop bleeding)
- Headache, dizziness and sensation of spinning
- Paresthesia (an abnormal sensation of the body, such as numbness, tingling or burning)
- Heartburn, warmth, abdominal pains, diarrhea
- Nausea (feel like vomiting), gastritis (inflammation of the stomach)
- Constipation, vomiting, stomach and/ or duodenal ulcer
- Prolonged bleeding time
- Rash and itching
- Thrombotic thrombocytopenic purpura (TTP) - a rare blood disorder where blood clots form in small vessels throughout the body. This side effect is very rare.

Most frequently reported undesirable effects are the bleeding symptoms, mainly in the first month of therapy. This is not the complete list of possible side effects. Please refer to your doctor or pharmacist for more detail or if you encounter any side effect not listed here.

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).

Storage and Disposal of Clopidogrel Actavis

- Storage

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 carton and blister after 'EXP'. The expiry date refers to the last day of that month.

Store below 25°C, in the original package.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose if medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Clopidogrel Actavis film-coated tablets are pink, round, biconvex film-coated tablets, 9.0 mm in diameter, with an 'I' engraved on one side of the tablets.

- Ingredients

- Active ingredient:
Each film-coated tablet Clopidogrel Actavis contains Clopidogrel Bisulphate 97.87 mg (equivalent to 75.0 mg Clopidogrel base) as active substance.

- Inactive ingredients:
Macrogol 3350, Microcrystalline Cellulose, Iron Oxide Red, Titanium dioxide, Glycerol Dibehenate, Lecithin, Crospovidone, Polyvinyl Alcohol, Lactose Anhydrous, Talc

- MAL number

MAL20102092A

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Product Registration Holder

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