

PLACTA TABLET 75MG

Clopidogrel (75 mg)

What is in this leaflet

1. What Placta is used for
2. How Placta works
3. Before you use Placta
4. How to take Placta
5. While you are using Placta
6. Side Effects
7. Storage and Disposal of Placta
8. Product description
9. Manufacturer and Product Registration Holder
10. Date of Revision

What Placta is used for

Placta 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 Placta works

Placta is a medicinal product containing active ingredient clopidogrel, 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 Placta

-When you must not take it

Do not use Placta 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 take it

Consult your doctor or pharmacist before taking Placta 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 Placta.

- You have planned for any operation and the blood thinning effect is not desirable. You doctor may ask you to discontinue the treatment with Placta 5 days prior to operation.

- You will be undergoing dental surgery and before starting the treatment with new medicinal product.

-Taking other medicines

Placta 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 take Placta

-How much to take

You should take a single daily dose of Placta 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:

Placta is not recommended for person below the age of 18.

-When to take it

Placta should be taken at the same time every day.

-How long to take it

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

-If you forget to take 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 take 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 Placta

-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

Placta 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 Placta to affect unfavourably the ability to drive and use machine.

PLACTA TABLET 75MG

Clopidogrel (75 mg)

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

Storage and Disposal of Placta

-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 30°C, in the original package.

-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

Placta 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 tablet 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 No.

MAL20102092AZ

Manufacturer

Actavis Ltd

BLB016 Bulebel Industrial Estate, Zejtun ZTN 3000, Malta

Product Registration Holder

DCH Auriga (Malaysia) Sdn. Bhd.

Lot 6, Persiaran Perusahaan Seksyen 23, 40300 Shah Alam Selangor, Malaysia

Date of Revision

12/07/2023

Serial Number

NPRA(R2/1)190723/203