

i PACKAGE LEAFLET:
Information for the patient

CLOPIDOLUT

Film-coated tablets - 75 mg

(Clopidogrel besilate)

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- 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.

In this leaflet:

1. What Clopidolul is and what it is used for
2. Before you take Clopidolul
3. How to take Clopidolul
4. Possible side effects
5. How to store Clopidolul
6. Further information

1. WHAT CLOPIDOLUT IS AND WHAT IT IS USED FOR

Clopidogrel 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).

Clopidolul 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).

You have been prescribed this medicine 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.

2. BEFORE YOU TAKE CLOPIDOLUT

Do not take Clopidolul:

- If you are **allergic** (hypersensitive) to clopidogrel or any of the other ingredients of the tablet;
- 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 this medicine.

Take special care with Clopidolul:

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

- if you have an increased risk of bleeding such as
 - a medical condition that puts you at **increased 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 are taking **other medicines** (see section 2: Taking other medicines).
- if you have **kidney or liver disease**.

While you are taking Clopidolul:

- You should tell your doctor if a surgery (including dental) is planned.
- You should also tell your doctor immediately if you develop 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.
- Please tell your doctor or pharmacist if you notice any side effects not listed under section 4 (POSSIBLE SIDE EFFECTS) of this leaflet or if a side effects affects you severely.

Children or adolescents

This medicine is not intended for use in children or adolescents.

Taking other medicines

Some other medicines may influence the use of Clopidolul or vice versa.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

The concomitant use of oral anticoagulants (medicines to prevent blood clotting) is not recommended.

You should specifically tell your doctor if you take **non-steroidal anti-inflammatory medicine**, usually used to treat painful and/or inflammatory conditions of muscle or joints or if you take **heparin** or **any other medicine** used to prevent blood clotting or if you take a proton pump inhibitor (e.g. omeprazole) for upset stomach. If you have experienced severe chest pain (unstable angina or heart attack), you may be prescribed Clopidolul 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.

Taking Clopidolul with food and drink

Food and meals have no influence. This medicine may be taken with or without food.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

It is preferable not to use this product during pregnancy and breast-feeding.

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

While taking Clopidolul, consult your doctor about the breast-feeding of a baby.

Driving and using machines

This medicine is unlikely to affect your ability to drive or to use machines.

Important information about some of the ingredients of this medicinal product:

Clopidolul contains lactose. If you have been told by your doctor that you have an intolerance to some sugars (e.g. lactose), contact your doctor before taking this medicine.

3. HOW TO TAKE CLOPIDOLUT

Always take the tablets 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 (4 tablets of 75 mg) once at the start of treatment. Then, the usual dose is one 75-mg per day to be taken orally with or without food, and at the same time each day. You should take the tablet for as long as your doctor continues to prescribe it.

If you take more Clopidolul than you should

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

If you forget to take Clopidolul

If you forget to take a dose, 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 individual doses.

If you stop taking Clopidolul

Do not stop the treatment. Contact your doctor or pharmacist before stopping.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Clopidolul 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: Take special care with Clopidolul).
- 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 (affects 1 to 10 patients in 100) 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 Clopidolul:

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 this is usually of no concern. **However, if you are concerned by your bleeding, you should contact your doctor straightaway** (see section 2: Take special care with Clopidolul).

Other side effects reported with Clopidolul are

Common side effects (affects 1 to 10 patients in 100):

- Diarrhoea, abdominal pain, indigestion or heartburn.

Uncommon side effects (affects 1 to 10 patients in 1,000):

- Headache, stomach ulcer, vomiting, nausea, constipation, excessive gas in stomach or intestines, rashes, itching, dizziness, abnormal sensitivity to touch.

Rare side effect (affects 1 to 10 patients in 10,000):

- Vertigo.

Very rare side effects (affects less than 1 patient in 10,000):

- Jaundice, severe abdominal pain with or without back pain, fever, breathing difficulties (sometimes associated with cough), generalised allergic reactions, swelling in the mouth, blisters of the skin, skin allergy,
- inflammation of the mouth (stomatitis), decrease in blood pressure, confusion, hallucinations, joint pain, muscular pain, changes in the way things taste.

Other side effects:

In addition, your doctor may identify changes in your blood or urine test results.

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.

5. HOW TO STORE CLOPIDOLUT

Keep out of the reach and sight of children.

Do not use Clopidolul after the expiry date which is stated on the package.

Store below 30°C.

Store in original package in order to protect from moisture.

6. FURTHER INFORMATION

What Clopidolul contains

The active substance is clopidogrel.

1 film-coated tablet contains 75 mg of clopidogrel as clopidogrel besilate.

The other ingredients are:

Core: Microcrystalline cellulose, crospovidone (type A), colloidal anhydrous silica, pregelatinised starch (maize), stearic acid.

Coating: Carnauba wax, hypromellose, lactose monohydrate, titanium dioxide (E 171), triacetin (E 1518), red iron oxide (E 172).

Contents of the pack

Box with 20 or 30 film – coated tablets.

Marketing Authorisation Holder and Manufacturer



Profarma sh.a.
Rruga „Myslym Keta“
Tel. Fax: 00 355 4 23 62 800
Tirana – Albania

This leaflet was last approved in August 2014.