

PACKAGE LEAFLET

Package leaflet: Information for the patient

Clopidogrel 75 mg 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 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 have any side effects, including any side effects not listed in this leaflet, talk to your doctor or pharmacist. See section 4.

What is in this leaflet:

1. What Clopidogrel is and what it is used for
2. What you need to know before you take Clopidogrel
3. How to take Clopidogrel
4. Possible side effects
5. How to store Clopidogrel
6. Contents of the pack and other information

1. What Clopidogrel is and what it is used for

Clopidogrel belongs to a group of medicines called antiplatelet medicines. 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 medicines reduce the chances of blood clots forming (a process called thrombosis).

Clopidogrel 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 Clopidogrel 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 aspirin (also known as acetylsalicylic acid, 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 e.g. warfarin) 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 clopidogrel and acetylsalicylic acid for this condition. Your doctor should have prescribed clopidogrel 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 Clopidogrel

Do not take Clopidogrel

- If you are allergic to clopidogrel or any of the other ingredients of this medicine (listed in section 6)

- If you suffer from severe liver disease
- If you have a medical condition that is currently causing bleeding such as a stomach ulcer or bleeding within the brain.

If you think any of these apply to you, or if you are in any doubt at all, consult your doctor before taking Clopidogrel.

Warnings and precautions

Talk to your doctor or pharmacist before taking this medicine:

- 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 Clopidogrel:

- You should tell your doctor if you plan to have surgery (including dental surgery)
- 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

Do not give this medicine to children because it does not work for children.

Other medicines and Clopidogrel

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 Clopidogrel or vice versa.

You should specifically tell your doctor if you take:

- medicines that may increase your risk of bleeding such as:
 - 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
 - ticlopidine, other antiplatelet agent
 - a selective serotonin reuptake inhibitor (including but not restricted to fluoxetine or fluvoxamine), medicines usually used to treat depression
- omeprazole or esomeprazole, medicines to treat upset stomach
- fluconazole or voriconazole, medicines to treat fungal infections
- efavirenz, a medicine to treat HIV (human immunodeficiency virus) infections
- carbamazepine a medicine to treat some forms of epilepsy
- moclobemide a medicine to treat depression
- repaglinide, medicine to treat diabetes

- paclitaxel, medicine to treat cancer.

If you have experienced severe chest pain (unstable angina or heart attack), you may be prescribed this medicine 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.

Pregnancy and breast-feeding

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

Pregnancy

It is preferable not to use Clopidogrel during pregnancy.

If you become pregnant while taking this medicine, consult your doctor immediately.

Breast-feeding

Breast-feeding should not be continued while taking this medicine, consult your doctor about breast-feeding your baby.

Driving and using machines

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

Clopidogrel contains lactose and hydrogenated castor oil.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Hydrogenated castor oil may cause stomach upset and diarrhoea.

3. How to take Clopidogrel

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults

The recommended dose, including for patients with a condition called 'atrial fibrillation' (an irregular heartbeat), is one 75 mg tablet of Clopidogrel per day to be taken orally with or without food, and at the same time each day.

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 recommended dose is one 75 mg tablet of Clopidogrel per day as described above.

You should take this medicine for as long as your doctor continues to prescribe it.

If you take more Clopidogrel than you should

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

If you forget to take Clopidogrel

If you forget to take a dose of Clopidogrel, 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 a forgotten tablet.

If you stop taking Clopidogrel

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, this medicine can cause side effects, although not everybody gets them.

Contact your doctor immediately if you experience:

- Fever, severe chills, sore throat or mouth ulcers, 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 'Warning and precautions').
- Swelling in the mouth, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing or skin disorders such as rashes and itching of the skin. These may be the signs of an allergic reaction.
- Severe skin reaction with painful red areas (face, armpits and groin), bleeding in the lips, eyes, mouth, nose and genitals, large and severe blisters and peeling of layers of skin, this is accompanied by rapid appearance of areas of red skin studded with small blisters filled with white/yellow fluid, fever and chills, aching muscles and generally feeling unwell. These may be sign of Toxic Epidermal Necrolysis (TEN), Stevens Johnson Syndrome (SJS), erythema multiforme, or Acute Generalised Exanthematous Pustulosis (AGEP).
- Severe upper stomach pain, that spreads to the back. This may be a sign of pancreatitis.
- Burning pain in the middle or upper stomach between meals or at night, bloating, heartburn. These may be signs of stomach or intestinal ulcer.
- Breathing difficulties sometimes associated with cough usually dry and nonproductive, weight loss, fever, and general feeling of illness. These may be signs of serious problems with the lungs.
- Unusual behaviour, seizures, paralysis of one side of the body, tingling or numbness of the hands or feet, visual disturbance, difficulty in speaking, reading and writing, seeing feeling or hearing things that are not there (hallucination). These may be sign of thrombotic thrombocytopenic purpura (TTP).

The most common side effect reported with this medicine is bleeding (may affect up to 1 in 10 people).

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 small number of cases, bleeding in the eye, inside the head, the lung or the joints has also been reported. If you notice a sudden severe headache with nausea and vomiting, temporary loss of vision, loss of consciousness, dark tar like stool, blood in the vomit, you should contact your doctor straightaway.

If you experience prolonged bleeding when taking Clopidogrel

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 'Warning and precautions').

Other side effects include:

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, vomiting, nausea, constipation, excessive gas in stomach or intestines, rashes, itching, dizziness, sensation of tingling and numbness.

Rare side effects (may affect up to 1 in 1,000 people):

A feeling of dizziness or spinning (vertigo), enlarged breasts in men.

Very rare side effects (may affect up to 1 in 10,000 people):

Fever, sore mouth (stomatitis), narrowing or blockage of blood vessels (vasculitis), decrease in blood pressure, confusion, seeing, feeling or hearing things that are not there (hallucinations), joint pain, muscular pain, taste disorders.

Side effects with frequency not known (frequency cannot be estimated from the available data):

Hypersensitivity reactions with chest or abdominal pain.

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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517; website: www.hpra.ie; e-mail: medsafety@hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Clopidogrel

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

Do not store this medicine above 25°C. Store in original container in order to protect it from light.

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 to protect the environment.

HDPE bottles: Use within 50 days of opening.

6. Contents of the pack and other information**What Clopidogrel contains**

- The active substance is clopidogrel. Each tablet contains 75 mg of clopidogrel (as hydrobromide monohydrate)
 - The other ingredients (see section 2 'Clopidogrel contains lactose and hydrogenated castor oil) are castor oil hydrogenated; pregelatinised maize starch; cellulose, microcrystalline; mannitol (E421); polysorbate 80 (E433), povidone, crospovidone. The coating includes lactose monohydrate; hypromellose (E464); titanium dioxide (E171); triacetin (E1518).

What Clopidogrel looks like and contents of the pack

This medicine is in the form of a film-coated tablet.

Clopidogrel 75 mg Film-coated tablets are white, round, biconvex film coated tablets, debossed with 'CB' over '75' on one side and 'G' on the other side of the tablet. Clopidogrel is available in blister packs of 7, 10, 14, 20, 28, 30, 50, 56, 84, 98, 112 tablets, or in perforated unit dose blisters in pack sizes of 30 x 1 or 50 x 1 or calendar packs of 28 tablets and bottles of 30, 50, 60, 84, 90, 100, 500 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

McDermott Laboratories Limited t/a Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13

This medicinal product is authorised in the Member States of the EEA under the following names:

Belgium	Clopidogrel HBr Mylan 75 mg filmomhulde tabletten
Cyprus	Clopidogrel Vale Pharmaceuticals 75 mg Film-coated Tablets
Czech Republic	Clopimyl 75 mg potahované tablety
Denmark	Clopidogrel “Generics” filmovertrukne tabletter 75 mg
Finland	Clopidogrel Generics 75 mg Film-coated tablet
France	Clopidogrel Mylan Pharma 75 mg, comprimé pellicule
Germany	Clopidogrel dura 75 mg Filmtabletten
Greece	Clopidogrel / Generics Film-coated Tablets 75mg/TAB
Iceland	Clopidogrel Generics 75 mg filmuhúðaðar töflur
Ireland	Clopidogrel 75 mg Film-coated Tablets
Italy	Clopidogrel Mylan Generics 75mg Compresse rivestite con film
Luxemburg	Clopidogrel HBr Mylan 75 mg comprimé pellicule
Malta	Clopidogrel Mylan 75 mg Film-coated Tablets
Portugal	Clopidogrel Anova 75 mg comprimido revestido por película
Slovakia	Clopidogrel Generics 75mg
Spain	Clopidogrel MYLAN Pharmaceuticals 75 mg comprimidos recubiertos con película EFG
Sweden	Clopidogrel Generics 75 mg filmdragerade tabletter
The Netherlands	Clopidogrel Mylan 75 mg, filmomhulde tabletten
United Kingdom	Clopidogrel 75 mg Film-coated Tablets

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