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What is Clopidogrel and is what it is used for

Clopidogrel belongs to a group of medicines called antiplatelet medicinal products. Platelets are very small structures in the blood which clump together during blood clotting. By preventing this clumping, antiplatelet medicinal products reduce the chances of blood clots forming (a process called thrombosis).

Clopidogrel is taken by adults to prevent blood clots 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 previously 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 an antiplatelet medicine (a substance present in many medicines used to relieve pain and inflammation, as well as to prevent blood clotting) by your doctor.
- You have an irregular heartbeat, a condition called 'atrial fibrillation', and you cannot take anticoagulants (medicines which prevent new blood clots), you should be given CLOPIDOGREL and acetylsalicylic acid for this purpose.
- You have a condition called 'atrial fibrillation', and you cannot take anticoagulants, you 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 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 Clopidogrel.

Warnings and precautions

If any of the precautions mentioned below apply to you, talk to your doctor or pharmacist before taking Clopidogrel.

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 disorder that makes you at risk to internal bleeding (bleeding inside any tissues, organs or joints of your body),
- a serious recent injury,
- a serious 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 medicines used to treat your disease.

While you are taking Clopidogrel:

- You should tell your doctor if a surgery (including dental) is planned.
- 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, and 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.

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.

Special information on other medicines may influence the use of Clopidogrel or vice versa.

You should specifically tell your doctor if you take medicines that may increase the risk of bleeding such as:

- oral anticoagulants, medicines used to reduce blood clotting, a non-steroidal anti-inflammatory medicine, usually used to treat pain and inflammatory conditions of muscles or joints, heparin or any other injectable medicine used to reduce blood clotting, anticoagulants (medicines which prevent new blood clots) such as 'vitamin K antagonists' which prevent new clots from forming and prevent existing clots from growing up into a bigger problem (called 'atrial fibrillation', and you cannot take anticoagulants, you should be given CLOPIDOGREL and acetylsalicylic acid for this purpose).

- omeprazole or esomeprazole, medicines to treat upset stomach, reflux or vomiting, medicines to treat fungal infections.
- efavirenz, a medicine to treat HIV (human immunodeficiency virus) infections, carbamazepine, a medicine to treat some forms of epilepsy, mood stabilizers, medicine to treat depression, reboxetine, medicine to treat depression, paclitaxel, medicine to treat cancer.

If you have experienced severe chest pain (unstable angina or heart attack), you may be prescribed CLOPIDOGREL in combination with acetylsalicylic acid, a substance that prevents many medicines used to relieve pain and lower fever. An occasional use of acetylsalicylic acid (75 mg), maximum 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.

Clopidogrel with food and drink

Clopidogrel may be taken with or without food.

Pregnancy and breast-feeding and fertility

It is preferable not to take this product during pregnancy.

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

You should not breast-feed while taking this medicine.

If you are breastfeeding or planning to breast-feed, talk to your doctor before taking this medicine.

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

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 (unrelated to heart or air 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 Clopidogrel 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, 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 taking Clopidogrel without discussing it with your doctor or pharmacist before stopping.

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

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, 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 the eye (jaundice), whether or not associated with bleeding which appears under the skin as red pinpoint dots and/or confusion (see section 2 "Warnings and precautions").
- swelling in the mouth or skin disorders such as rashes and itching, blister of the skin.
- these may be due to rare decrease of some blood cells.

The most common side effect reported with clopidogrel is bleeding. Bleeding may occur as bleeding in the stomach or bowels, bruising, haematomata (unusual bleeding or bruising under the skin), nose bleed, in the skin. 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 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 not a concern. However, if you are concerned by your bleeding, you should contact your doctor straightaway (see section 2 "Warnings 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, stomach pain, vomiting, nausea, constipation, excessive gas in stomach or intestine, rashes, itching, dizziness, sensation of tingling and numbness.

Rare side effect (may affect up to 1 in 1000 people):
- Vertigo, enlarged breasts in males.

Very rare side effects (may affect up to 1 in 10,000 people):
- Jaundice, severe abdominal pain with or without back pain; fever, breathing difficulties sometimes associated with cough; generalized allergic reactions (for example, overall sensation of heat with sudden general discomfort until fainting); swelling in the mouth; bruises of the skin; allergy; sore mouth ( stomatitis); decrease in blood pressure; confusion; hallucinations; Joint pain; muscular pain; changes in taste of food.

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 the national reporting system listed in appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

The United Kingdom
Yellow Card Scheme.
Website: www.mhra.gov.uk/yellcard

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

Store below 30°C. Bottle pack: Use within 6 months after first opening the bottle.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer need. These measures will help protect the environment.

6. Contents of the pack and other information

What Clopidogrel contains
The active substance is clopidogrel. Each tablet contains 75 mg of clopidogrel (as clopidogrel bisulfate).
- The other ingredients are microcrystalline cellulose (grade 113), macrogol, low substituted hydroxypropyl cellulose, croscovidone (type A), macrogol 6000, hydroxypropyl cellulose, lactose monohydrate (see section 2 "Clopidogrel contains Lactose", hypromellose (15 cp), titanium dioxide (E171), iron oxides red (E172).

What Clopidogrel looks like and contains of the pack
Film-coated tablet.
- Pink coloured, round, biconvex, bevel edged, film-coated tablets debossed with 'E' on one side and '34' on the other side.
- Clopidogrel 75 mg film-coated tablets are available in blister packs containing 14, 28, 30, 50, 56, 84, 100 & 500 film-coated tablets and bottle packs containing 30, 100 & 500 film-coated tablets.
- Not all pack sizes may be marketed.

Marketing Authorisation Holder
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Manufacturer
APL Swift Services (Malt) Limited
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