Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

1. What is Clopidogrel and what is it used for

Clopidogrel is taken by adults to prevent blood clots (thrombi) forming (a process called thrombosis). By preventing this clumping, platelets are very small structures in the blood which clump together during blood clotting. By preventing this clumping, platelets can lead to atherothrombotic events (such as stroke, heart attack, or death).

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).

2. What you need to know before you take Clopidogrel

If you have had a clot in an artery of your brain (ischemic stroke) which occurred within the last seven days.

• if you have had a clot in an artery of your brain (ischemic stroke) which occurred within the last seven days.

• if you have a condition of hardening of arteries (also known as atherosclerosis), and you should specifically tell your doctor if you take:

• oral anticoagulants, medicines used to reduce blood clotting, a non-steroidal anti-inflammatory medicine, usually used to treat painful and/or inflammatory conditions of muscles or joints, and

• if you have experienced severe chest pain (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 may 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.

• you should not breast-feed while taking this medicine.

3. Possible side effects

• if you have had an allergy or reaction to any medicine used to treat your disease.

• if you have had a past medical history of non-traumatic brain hemorrhage

While you are taking Clopidogrel:

• You should tell your doctor or a surgeon (including dental) it is preferable not to take this product during pregnancy.

You should also tell your doctor immediately if you develop a condition known as 'thrombotic Thrombocytoopenic Purpura or TTP') that includes fever and bruising under the skin that may appear as red pin point 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’).

• if you are allergic (hypersensitive) to clopidogrel or any of the ingredients of this medicine (listed in section 6).

4. How to take Clopidogrel

• if you are allergic (hypersensitive) 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 have 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 situations mentioned below apply to you, talk to your doctor or pharmacist or nurse before taking Clopidogrel:

• if you have a risk of bleeding such as:

• a planned surgery (including dental) in the next seven days.

• if you have haemophilia or any other blood disorder that makes you prone to internal bleeding such as a stomach ulcer.

• if you have undergone a planned surgery (including dental) in the next seven days.

• if you have a risk of major bleeding.

• if you are allergic (hypersensitive) to acetylsalicylic acid if you cannot take ‘oral anticoagulants’ and you do not want to take Clopidogrel and acetylsalicylic acid for this condition. Your doctor may be 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.

• if you have or have had a blood disorder that makes you prone to internal bleeding such as a stomach ulcer or bleeding within the brain.

• if you have had a risk of major bleeding.

• if you have had a medical condition that is currently causing bleeding such as a stomach ulcer or bleeding within the brain.

• if you have 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 situations mentioned below apply to you, talk to your doctor or pharmacist or nurse 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 bleeding disorder that makes you prone to internal bleeding (bleeding inside your tissues, organs or joints of your body).

• a recent serious injury.

• a recent surgery (including dental).
Clopidogrel contains lactose

Clopidogrel contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

“Clopidogrel contains hydrogenated castor oil
This may cause stomach upset or 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. 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 or 600 mg of Clopidogrel (1 or 2 tablets of 305 mg or 4 or 8 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.

If you have experienced symptoms of a stroke which go away within a short period of time (also known as transient ischemic attack) or an ischemic stroke mild in severity, 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 with acetylsalicylic acid for 3 weeks.

Then the physician would prescribe either Clopidogrel alone or acetylsalicylic acid alone.

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, 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, 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 “Warnings and precautions”).
- 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 reported with clopidogrel is bleeding. Bleeding may occur as bleeding in the stomach or bowels, bruising, haematomas (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 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 “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 ulcer, vomiting, nausea, constipation, excessive gas in stomach or intestines, 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, abdominal or chest pain associated with vomiting, fever, breathing difficulties sometimes associated with cough; generalised allergic reactions (for example, overall sensation of heat with sudden general discomfort until fainting); swelling in the mouth; blisters of the skin; skin allergy; sore mouth (stomatitis); decrease in blood pressure; confusion; hallucinations; joint pain; muscular pain; changes in taste or loss of taste of food.

Side effects with frequency not known (frequency cannot be estimated from the available data):
Hypersensitivity reactions with chest or abdominal pain, persistent low blood pressure, high blood pressure, fever, kidney disorders.

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

Reporting 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 report side effects directly via Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. 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 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 throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Clopidogrel contains

- The active substance is clopidogrel. Each film-coated tablet contains 75 mg of clopidogrel (as clopidogrel bisulfate).

- The other ingredients are microcrystalline cellulose (grade 113), mannitol, low substituted hydroxypropylcellulose, crospovidone (type A), macrogol 6000, hydrogenated castor oil, lactose monohydrate (see section 2 “Clopidogrel contains Lactose”), hypromellose (15 cp), titanium dioxide (E171), talc, iron oxide red (E172).

What Clopidogrel looks like and contents of the pack

Each pack contains 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

Milpharm Limited
Ares Block, Odyssey Business Park
West End Road
Ruislip HA4 6QD
United Kingdom

Manufacturer

APL Swift Services (Malta) Limited
HF26, Hal Far Industrial Estate, Hal Far Birzebbuga, BBG 3000
Malta
or
Milpharm Limited
Ares Block, Odyssey Business Park
West End Road
Ruislip HA4 6QD
United Kingdom

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