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 or nurse.
- 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 get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Clopidogrel 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 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 (thromb) forming in hardened blood vessels (arteries) that are 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 (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. An occasional use of acetylsalicylic acid (no more than 1000 mg in any 24 hours) may be recommended to reduce the risk of angina or myocardial infarction), which is stated on the carton after EXP.

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 inside 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.

Warning and precautions

If any of the warnings 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 blood disorder that makes you prone to internal bleeding (bleeding inside any tissues, organs or joints of your body),
- a 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 a surgery (including dental) is planned.
- You should also tell your doctor immediately if you develop a medical condition such as a recent surgery which may increase your risk of bleeding and which may require you to stop taking Clopidogrel or vice versa.

You should also tell your doctor immediately if you are given another medicine used to relieve pain and lower fever. An occasional use of acetylsalicylic acid (no more than 1000 mg in any 24 hours) may be recommended to reduce the risk of angina or myocardial infarction, which is stated on the carton after EXP.

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

You should specifically tell your doctor if you take any other 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 pain 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, medicine to treat depression,
- rapagindine, medicine to treat diabetes,
- sotalol, medicine to treat heart failure,
- anti-retroviral medicines (medicines to treat HIV infections).

If you have experienced severe chest pain (unstable angina or heart attack), you may be prescribed Clopidogel in combination with a substance known as acetylsalicylic acid, a substance present in many medicines used to relieve pain and lower fever. An occasional use of acetylsalicylic acid (no more than 1000 mg in any 24 hours) may be recommended to reduce the risk of angina or myocardial infarction, which is stated on the carton after EXP.

If you are breastfeeding or planning to breastfeed, you should contact your doctor before taking this medicine. See section 4.

Children and adolescents

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

Pregnancy and breast-feeding

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.

The expected frequency of adverse events is usually of no concern. However, you should contact your doctor or the nearest hospital emergency department because of the increased risk of bleeding.

You should also tell your doctor immediately if you are given another medicine used to relieve pain and lower fever. An occasional use of acetylsalicylic acid (no more than 1000 mg in any 24 hours) may be recommended to reduce the risk of angina or myocardial infarction, which is stated on the carton after EXP.

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 such as, cutting yourself, shaving, this is usually of no concern. However, it is important to tell your doctor if you are concerned by your bleeding, you should contact your doctor straightaway (see section 4).

Other medicines may influence the use of Clopidogrel or vice versa.

3. How to take Clopidogrel

Clopidogrel contain hydrogenated castor oil (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, medicine to treat depression,
- rapagindine, medicine to treat diabetes,
- sotalol, medicine to treat heart failure,
- anti-retroviral medicines (medicines to treat HIV infections).

If you have experienced severe chest pain (unstable angina or heart attack), you may be prescribed Clopidogel in combination with a substance known as acetylsalicylic acid, a substance present in many medicines used to relieve pain and lower fever. An occasional use of acetylsalicylic acid (no more than 1000 mg in any 24 hours) may be recommended to reduce the risk of angina or myocardial infarction, which is stated on the carton after EXP.

If you are breastfeeding or planning to breastfeed, you should contact your doctor before taking this medicine. See section 4.

Clopidogrel with food and drink

It is preferable not to take this product during pregnancy.

Pregnancy and breast-feeding

This leaflet was last revised in 08/2019.
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 75 mg 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 500 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, 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 tablet 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 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.
- less than usual bleeding due to rare decrease of some blood cells.
- long list of possible 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 pin-point 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, haematoma (unusual bruising or blurring 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 or pharmacist straightaway (see section 2 'Warnings and precautions').

Other side effects include:

- Abnormal loss of blood (may affect up to 10 persons in 10,000 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, rash, itching, dizziness, sensation of tingling or numbness.

Rare side effect (may affect up to 1 in 100 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 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); decreased 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 sugar symptoms.

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 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 these medicines.

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 and blister packs. 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, croscarmellose (type A), macrogol 6000, hydrogenated castor oil, lactose monohydrate (see section 2 'Clopidogrel contains Lactose').
- Titan dioxide (E171), talc, iron oxide red (E172).

What Clopidogrel looks like and contents of the pack
- Film-coated tablet.
- Pink coloured, round, biconvex, bevel edge, 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.

Note that all pack sizes may be marketed.

Marketing Authorisation Holder
Mipharm Limited
Arias Block, Odyssey Business Park
West End Road
Rudipal H44 Q02
United Kingdom

Manufacturer
APL Swift Services (Malta) Limited
HMP, Dar es Salaam Industrial Estate, Hai Far Birzebbuga, BBQ 3000 Malta
or
Mipharm Limited
Arias Block, Odyssey Business Park
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