Package leaflet: Information for the user

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

1. What Clopidogrel Viatris is and what it is used for

Clopidogrel Viatris contains clopidogrel and 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 Viatris 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 Viatris 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.
- You have an irregular heartbeat, a condition called ‘atrial fibrillation’, and you cannot take medicines known as ‘oral anticoagulants’ (vitamin K antagonists) 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 Viatris

Do not take Clopidogrel Viatris:

- 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 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 Viatris

Warnings and precautions

If any of the situations mentioned below apply to you, you should tell your doctor before taking Clopidogrel Viatris:

- 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 Viatris:

- 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 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.

Other medicines and Clopidogrel Viatris

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 Viatris 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, or other anti-retroviral medicines (used to treat HIV infections),
- carbamazepine, a medicine to treat some forms of epilepsy,
- moclobemide, medicine to treat depression.
- repaglinide, medicine to treat diabetes,
- paclitaxel, medicine to treat cancer.
- opioids: while you are treated with clopidogrel, you should inform your doctor before being prescribed any opioid (used to treat severe pain)
- rosuvastatin (used to lower your cholesterol level).

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

Clopidogrel Viatris with food and drink
Clopidogrel Viatris may be taken with or without food.

Pregnancy and breast-feeding
It is preferable not to take this medicine during pregnancy.

If you are pregnant or suspect that you are pregnant, you should tell your doctor or your pharmacist before taking Clopidogrel Viatris. If you become pregnant while taking Clopidogrel Viatris, 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 breast-feeding or planning to breast-feed, talk to your doctor before taking this medicine.

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

Driving and using machines
Clopidogrel Viatris is unlikely to affect your ability to drive or to use machines.

Clopidogrel Viatris 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 Clopidogrel Viatris

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 Clopidegrel Viatris 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 Viatris (4 tablets of 75 mg) once at the start of treatment. Then, the recommended dose is one 75-mg tablet of Clopidogrel Viatris per day as described above.

You should take Clopidogrel Viatris for as long as your doctor continues to prescribe it.

If you take more Clopidogrel Viatris 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 Viatris

If you forget to take a dose of Clopidogrel Viatris, 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 Viatris

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 Viatris 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 Clopidogrel Viatris

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; severe abdominal pain with or without back pain; 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 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 the Yellow Card Scheme at 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 Viatris

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

Refer to the storage conditions on the carton.
If Clopidogrel Viatris is supplied in PVC/PE/PVDC/aluminium blisters, store below 25°C.
If Clopidogrel Viatris is supplied in all aluminium blisters, it does not require any special storage conditions.

Do not use this medicine if you notice any visible sign of deterioration.

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.

6 Contents of the pack and other information

What Clopidogrel Viatris contains
The active substance is clopidogrel. Each tablet contains 75 mg of clopidogrel (as besilate).

The other ingredients are (see section 2 'Clopidogrel Viatris contains lactose'):
- Tablet core: hydroxypropylcellulose (E463), mannitol (E421), crospovidone (type A), citric acid monohydrate, microcrystalline cellulose, macrogol 6000, stearic acid, talc
- Tablet coating: lactose monohydrate (milk sugar), hypromellose (E464), triacetin (E1518), red iron oxide (E172) and titanium dioxide (E171),

What Clopidogrel Viatris looks like and contents of the pack

Clopidogrel Viatris film-coated tablets are pink, round and biconvex.
They are supplied in PVC/PE/PVDC/Alu blisters or in PA/ALL/PVC-Alu blisters packed in cartons containing 7, 14, 28, 30, 50, 56, 84, 90 or 100 film-coated tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturers:

Viatris,
Station Close,
Potters Bar,
EN6 1TL,
United Kingdom.

Manufacturers:
Pharmathen S.A.
6 Dervenakion
15351 Pallini Attiki
Greece

Or

Pharmathen International S.A
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