

Package leaflet: Information for the user

Clopidogrel Pensa 75 mg film-coated tablets

Clopidogrel

Read all of this leaflet carefully before you start using 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, 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 of the side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

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

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

Clopidogrel Pensa 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 Pensa is taken 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 Pensa 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 arteriosclerosis), 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.

2. What you need to know before you take Clopidogrel Pensa

Do not take Clopidogrel Pensa:

- 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 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 Pensa.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Clopidogrel Pensa:

- 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.

While you are taking Clopidogrel Pensa:

- 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

Clopidogrel Pensa is not intended for use in children or adolescents

Other medicines and Clopidogrel Pensa

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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

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 muscle or joints,
- heparin or any other injectable medicine used to reduce blood clotting,
- omeprazole, esomeprazole or cimetidine, medicines to treat upset stomach,
- fluconazole, voriconazole, ciprofloxacin, or chloramphenicol, medicines to treat bacterial and fungal infections,
- fluoxetine, fluvoxamine, or moclobemide, medicines to treat depression,
- carbamazepine, or oxcarbazepine, medicines to treat some forms of epilepsy,
- ticlopidine or prasugrel, other antiplatelet agents.

If you have experienced severe chest pain (unstable angina or heart attack), you may be prescribed Clopidogrel Pensa 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 1000 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 Pensa with food and drink and alcohol

Clopidogrel Pensa may be taken with or without food.

Pregnancy, breast-feeding and fertility

It is preferable not to use this product during pregnancy and breast-feeding.

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

While taking Clopidogrel Pensa, consult your doctor about the breast-feeding of a baby.

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.

Driving and using machines

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

Clopidogrel Pensa contains lactose-monohydrate.

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 Pensa

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 is one 75 mg tablet of Clopidogrel Pensa per day to be taken orally with or without food and at the same time each day.

In addition, if you have experienced severe chest pain (unstable angina or heart attack), your doctor may give you 300 mg of Clopidogrel Pensa (4 tablets of 75 mg) as a single dose at the start of the treatment.

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

If you take more Clopidogrel Pensa 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 Pensa

If you forget to take a dose of Clopidogrel Pensa, 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 the forgotten individual doses.

If you stop taking Clopidogrel Pensa

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, pharmacist or nurse.

4. Possible side effects

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

The frequency of possible side effects listed below is defined using the following convention:

- very common (affects more than 1 user in 10)
- common (affects 1 to 10 users in 100)
- uncommon (affects 1 to 10 users in 1,000)
- rare (affects 1 to 10 users in 10,000)
- very rare (affects less than 1 user in 10,000)
- not known (frequency cannot be estimated from the available data)

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 'Take special care with Clopidogrel Pensa).
- 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 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 Pensa

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 'Take special care with Clopidogrel Pensa').

Other side effects reported with clopidogrel are:

Common side effects: Diarrhoea, abdominal pain, indigestion or heartburn.

Uncommon side effects: Headache, stomach ulcer, vomiting, nausea, constipation, excessive gas in stomach or intestines, rashes, itching, dizziness, sensation of tingling and numbness.

Rare side effect: Vertigo.

Very rare side effects: Jaundice; severe abdominal pain with or without back pain; fever, breathing difficulties sometimes associated with cough; generalized allergic reactions; swelling in the mouth; blisters of the skin; skin allergy; inflammation of the mouth (stomatitis); decrease in blood pressure; confusion; hallucinations; joint pain; muscular pain; changes in the way things taste.

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, pharmacist or nurse. This includes any side effects not listed in this leaflet.

You can also report side effects directly via

Pharmacovigilance Section

Irish Medicines Board

Kevin O'Malley House

Earlsfort Centre

Earlsfort Terrace

IRL - Dublin 2

Tel: +353 1 6764971

Fax: +353 1 6762517

Website: www.imb.ie

e-mail: imbpharmacovigilance@imb.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Clopidogrel Pensa

Keep this medicine out of the sight and reach of children.

Do not store above 30°C.

Store in the original package in order to protect from moisture.

Do not use this medicine after the expiry date which is stated on the blisters and the carton after EXP. The expiry date refers to the last day of that month.

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 Pensa contains

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

The other ingredients are:

Tablet core:

Maize Starch, Pregelatinised
Cellulose, Microcrystalline
Crospovidone Type A
Silica, Colloidal Anhydrous
Stearic Acid Type 50

Film-coating:

Carnauba wax
Lactose monohydrate
Hypromellose (E464)
Titanium dioxide (E171)
Triacetin (E1518)
Iron oxide red (E172)

What Clopidogrel Pensa looks like and contents of the pack

Clopidogrel Pensa film-coated tablets are pink, round, biconvex, film-coated tablets with '75' embossed on one side and a diameter of approximately 8.3 mm.

Clopidogrel Pensa is available in blister packs of:
14, 28, 30, 50, 84, 90, 100 film-coated tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Pensa Pharma AB
Birger Jarlsgatan 22
114 34 Stockholm

Manufacturer:

Specifar S.A., 1, 28 Octovriou str., Ag. Varvara, 12351 Athens, Greece

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

SE, IT, IE: Clopidogrel Pensa

This leaflet was last revised in June 2014