

Package leaflet: Information for the user

CILOSTOL 100 mg tablets (Cilostazol)

This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

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

In this leaflet:

1. What CILOSTOL is and what it is used for
2. What you need to know before you take CILOSTOL
3. How to take CILOSTOL
4. Possible side effects
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1. What CILOSTOL is and what it is used for

CILOSTOL belongs to a group of medicines called phosphodiesterase type 3 inhibitors.

It has several actions which include widening of some blood vessels and reducing the clotting activity (clumping) of some blood cells, called platelets, inside your vessels.

You have been prescribed CILOSTOL for "intermittent claudication". Intermittent claudication is the cramp-like pain in your legs when you walk and is caused by insufficient blood supply in your legs. CILOSTOL can increase the distance you can walk without pain since it improves the blood circulation in your legs. CILOSTOL is only recommended for patients whose symptoms have not improved sufficiently after making life-style modifications (such as stopping smoking and increasing exercise) and after other appropriate interventions. It is important that you continue the modifications you have made to your life-style whilst taking cilostazol.

2. What you need to know before you take CILOSTOL

Do not take CILOSTOL

- If you are allergic to cilostazol or any of the other ingredients of this medicine (listed in section 6).
- If you have the condition "heart failure".

- If you have persistent chest pain at rest, or have had a “heart attack” or any heart surgery in the last six months.
- If you have now or previously suffered from blackouts due to heart disease, or any severe disturbances of the heartbeat.
- If you know that you have a condition which increases your risk of bleeding or bruising, such as:
 - Active stomach ulcer(s).
 - Stroke in the past six months.
 - Problems with your eyes if you have diabetes.
 - If your blood pressure is not well controlled.
 - If you are taking both acetylsalicylic acid and clopidogrel, or any combination of two or more medicines which can increase your risk of bleeding [ask your doctor or pharmacist if you are not sure].
- If you have severe kidney disease or moderate or severe liver disease.
- If you are pregnant.

Warnings and precautions

Talk to your doctor or pharmacist before taking CILOSTOL:

- If you have a severe heart problem or any problems with your heart beat.

During treatment with CILOSTOL make sure that

- If you need to have surgery including having teeth removed, tell your doctor or dentist that you are taking CILOSTOL.
- If you experience easy bruising or bleeding, stop taking CILOSTOL and tell your doctor.

Other medicines and CILOSTOL

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

You should specifically inform your doctor if you take some medicines usually used to treat painful and/or inflammatory conditions of muscle or joints, or if you take medicines to reduce blood clotting. These medicines include:

- acetylsalicylic acid
- clopidogrel
- anticoagulant medicines (e.g. warfarin, dabigatran, rivaroxaban, apixaban or low molecular weight heparins)

If you are taking such medicines with CILOSTOL your doctor may perform some routine blood tests.

Certain medicines may interfere CILOSTOL or make CILOSTOL less effective. CILOSTOL may do the same to other medicines. Before you start taking CILOSTOL, please tell your doctor if you are taking:

- erythromycin, clarithromycin or rifampicin (antibiotics)
- ketoconazole (to treat fungal infections)
- omeprazole (to treat excess acid in the stomach)
- diltiazem (to treat high blood pressure or chest pain)
- cisapride (to treat stomach disorders)

- lovastatin, simvastatin or atorvastatin (to treat high cholesterol in the blood)
- halofantrine (to treat malaria)
- pimozide (to treat mental illnesses)
- ergot derivatives (to treat migraine e.g. ergotamine, dihydroergotamine)
- carbamazepin or phenytoin (to treat convulsions)
- St. John's wort (a herbal remedy)

If you are not sure if this applies to your medicines ask your doctor or pharmacist.

Before you start taking CILOSTOL, please inform your doctor or pharmacist if you are taking medicines for high blood pressure because CILOSTOL may have an additional lowering effect on your blood pressure. If your blood pressure falls too low, this could cause a fast heartbeat. These medicines include:

- Diuretics (e.g., hydrochlorothiazide, furosemide)
- Calcium channel blockers (e.g., verapamil, amlodipine)
- ACE inhibitors (e.g., captopril, lisinopril)
- angiotensin II receptor blockers (e.g., valsartan, candesartan)
- Beta blockers (e.g., labetalol, carvedilol);

It may still be all right for you to take the above mentioned medicines and CILOSTOL together and your doctor will be able to decide what is suitable for you.

CILOSTOL with food and drink and alcohol

CILOSTOL tablets should be taken 30 minutes before breakfast and the evening meal.

Always take your tablets with a drink of water.

CILOSTOL **MUST NOT** be used during pregnancy.

For breast-feeding mothers use of CILOSTOL is **NOT RECOMMENDED**.

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

CILOSTOL may cause dizziness. If you feel dizzy after taking CILOSTOL tablets, **DO NOT** drive and do not use any tools or machines and inform your doctor or pharmacist.

3. How to take CILOSTOL

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 100 mg tablet twice a day (morning and evening). This dose does not need to be changed for elderly people. However, your doctor may prescribe a lower dose if you are taking other medicines which may have an effect on CILOSTOL.
- CILOSTOL tablets should be taken 30 minutes before breakfast and the evening meal. Always take your tablets with a drink of water.

Some benefits of taking CILOSTOL may be felt within 4-12 weeks of treatment. Your doctor will assess your progress after 3 months of treatment and may recommend that you discontinue cilostazol if the effect of treatment is insufficient.

Use in children and adolescents.

CILOSTOL is not suitable for children.

If you take more CILOSTOL than you should

If for any reason you have taken more CILOSTOL tablets than you should, you may have signs and symptoms such as severe headache, diarrhea, a fall in blood pressure and irregularities of your heartbeat.

If you have taken more tablets than your prescribed dose, contact your doctor or your local hospital immediately. Remember to take the pack with you so that it is clear what medicine you have taken.

If you forget to take CILOSTOL

If you miss a dose, do not worry; wait until the next dose to take your next tablet and then carry on as normal. **DO NOT** take a double dose to make up for a forgotten tablet.

If you stop taking CILOSTOL

If you stop taking CILOSTOL the pain in your legs may come back or get worse. Therefore, you should only stop taking CILOSTOL if you notice side effects requiring urgent medical attention (see section 4) or if your doctor tells you to.

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.

If any of the following side effects happen, you may need urgent medical attention. Stop taking CILOSTOL and contact with a doctor or go to the nearest hospital immediately.

- stroke
- heart attack
- heart problems which can cause shortness of breath or ankle swelling
- irregular heart beat (new or worsening)
- noticeable bleeding
- easy bruising
- serious illness with blistering of the skin, mouth, eyes and genitals
- yellowing of the skin or whites of the eyes caused by liver or blood problems (jaundice)

You should also tell your doctor immediately if you have fever or sore throat. You may need to have some blood tests and your doctor will decide on your further treatment.

The following side effects have been reported for CILOSTOL. You should tell your doctor as soon as possible:

Very common side effects (affecting more than 1 in 10 people)

- headache
- abnormal stools
- diarrhea

Common side effects (affecting less than 1 in 10, but more than 1 in 100 people)

- fast heart beat
- heart pounding (palpitation)
- chest pain
- dizziness
- sore throat
- runny nose (rhinitis)
- abdominal pain
- abdominal discomfort (indigestion)
- feeling or being sick (nausea or vomiting)
- loss of appetite (anorexia)
- excessive burping or wind (flatulence)
- swelling of ankles, feet or face
- rash or changes in appearance of the skin
- itchy skin
- patchy bleeding in the skin
- general weakness.

Uncommon side effects (affecting less than 1 in 100, but more than 1 in 1,000 people)

- heart attack
- irregular heart heat (new or worsening)
- heart problems that can cause shortness of breath or ankle swelling
- pneumonia
- cough
- chills
- unexpected bleeding
- tendency to bleed (e.g., of the stomach, eye or muscle, nose bleed and blood in spit or urine)
- decrease in red cells in the blood
- dizziness on standing up
- fainting
- anxiety
- difficulty sleeping
- unusual dreams
- allergic reaction
- aches and pains
- diabetes and increased blood sugar
- stomach ache (gastritis)
- malaise

There may be a higher risk of bleeding into the eye in people with diabetes.

Rare side effects (affecting less than 1 in 1,000, but more than 1 in 10,000 people)

- tendency to bleed for longer than usual
- increase in the platelets in the blood
- problems with the kidneys

The following side effects have been reported during the use of CILOSTOL but it is not known how frequently they may occur:

- changes in the blood pressure
- decrease in red cells, white cells and platelets in your blood
- difficulty breathing
- difficulty moving
- fever
- hot flushes
- eczema and other skin rashes
- reduced sensation of the skin
- runny or sticky eyes (conjunctivitis)
- ringing in the ears (tinnitus)
- liver problems including hepatitis
- changes in the urine.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store CILOSTOL

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

Store below 25°C in the original package in order to protect from humidity.

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

Do not throw away any medicines of 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 CILOSTOL contains

- The active substance is cilostazol (I.N.N.). One tablet contains 100 mg cilostazol.
- The other ingredients are sorbitol, talc, microcrystalline cellulose, crospovidone, carmellose calcium, colloidal anhydrous silica, magnesium stearate and stearic acid.

What CILOSTOL 100 mg tablets is

White or almost white, round, biconvex and marked.

Your medicine is supplied in pack of 56 tablets.

Marketing Authorisation Holder and Manufacturer

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This leaflet was last reviewed in October 2013