

CILOSOL 100

Cilostazol (100 mg)

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What Cilosol 100 is used for

Cilosol 100 is used to treat intermittent claudication (a distinctive type of pain at the legs). It is usually caused by blockage of the blood vessels to the leg, hence the calf muscles are not receiving enough oxygen. The muscle pain or cramping happen whenever you walk some distance but the pain disappears when you rest. Cilosol 100 only works if there is no peripheral tissue death.

It is also used for prevention of recurrence of cerebral infarction (lack of oxygen supply to brain tissue), excluding cardiogenic cerebral embolism (an obstruction in brain artery by a plaque or blood clot which originates from the heart).

How Cilosol 100 works

Cilosol 100 inhibit platelet aggregation and hence inhibit the formation of blood clot or plaque that causing blockage in blood vessels.

Cilosol 100 increases blood flow in the occluded ankle, lower limbs and brain by dilating the blood vessels and hence to improve the blood circulation.

Before you use Cilosol 100

- When you must not use it

You must not take Cilosol 100 if:

- You are allergic (hypersensitive) to Cilostazol or any other ingredients of Cilosol 100
- You have congestive heart failure of any severity
- You have active pathologic bleeding such as bleeding

stomach ulcer and intracranial (bleeding to the brain)

- You have persistent chest pain at rest, or have had a “heart attack” or any heart surgery in the last six months.
- You have severe kidney disease
- You have moderate or severe liver disease.
- You are pregnant.

Pregnancy and breastfeeding

If you are pregnant, think you may be pregnant or if you are breastfeeding ask your doctor or pharmacist for advice before taking any medicine.

- Before you start to use it

Check with your doctor or pharmacist before taking your medicine if:

- You are allergic to Cilostazol, any other medications, or any of the ingredients in Cilosol 100.
- You have bleeding ulcers, bleeding in the brain, bleeding from any other part of your body, a low number of platelets in your blood, or any other condition that causes severe bleeding.
- You are having or have had any heart problem.
- You are having or have had severe kidney impairment.
- If you are pregnant, plan to become pregnant, or are breastfeeding.

- Taking other medicines

Please inform your doctor or pharmacist if you are taking any prescribed or non-prescription medicines, especially:

- Other antiplatelet or anticoagulant agent (e.g. acetylsalicylic acid, clopidogrel, heparin, warfarin, dabigatran, rivaroxaban or apixaban) for reduce risk of blood clotting
- 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)
- Carbamazepine or Phenytoin (to treat convulsions)
- St. John's Wort (herbal remedy)

How to use Cilosol 100

- How much to use

Always take Cilosol 100 exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The recommended dosage of Cilosol is 100mg twice daily taken at least half an hour before or two hours after breakfast and dinner. A dose of 50mg twice daily may be given by your doctor if you are taking some medicines concomitantly.

- When to use it

Cilosol 100 should be taken twice daily at least half an hour before or two hours after breakfast and dinner.

- How long to use it

You may start to feel the effect as early as 2 to 4 weeks after the initiation of therapy, but treatment for up to 12 weeks may be needed before a beneficial effect is experienced.

Your doctor may need to reassess you after 3 months of treatment with a view to discontinuing Cilosol 100 if an inadequate effect is observed or symptoms have not been improved.

- If you forget to use it

If you miss a dose, take the dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and follow your regular dosing schedule. You should never take two doses at one time.

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- If you use too much (overdose)

If you or anyone accidentally consumed too much Cilosol 100, please go to your nearest hospital for treatment as you may need medical assistance. Some of the signs of Cilosol overdose are: severe headache, diarrhea, hypotension (low blood pressure), tachycardia (unusual heart beat), and possibly cardiac arrhythmias (irregular heart beat).

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give Cilosol 100 to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Side effects

Like all medicines, Cilosol 100 can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

If any of the following side effects happen, you may need urgent medical attention. Stop taking Cilosol 100 and contact a doctor or go to the nearest hospital immediately:

- Stroke
- Heart attack

- Heart problems which can cause shortness of breath or ankle swelling
- Irregular heartbeat (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)

The following side effects have been reported for Cilosol 100:

Very common side effects:
Headache, abnormal stools, diarrhea

Common side effects:

Fast heartbeat, heart pounding, 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:

Heart attack, irregular heartbeat (new or worsening), heart problems, than 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 in sleeping, allergic reaction, aches and pains, diabetes and increased blood sugar, stomach ache (gastritis), malaise.

Rare side effects:

Tendency to bleed for longer than usual, increase in the platelets in the blood, problems with the kidneys.

Unknown side effects:

Changes in the blood pressure, decrease in red cells, white cells and platelets in your blood, difficulty in breathing, difficulty in 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.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835490, or visiting the website npra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Cilosol 100

-Storage

Keep medicines out of reach of children.

Store below 30°C.

-Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will protect the environment.

Product Description

- What it looks like

White, round, flat-faced, bevelled edge tablet with engraved 100 on one side and plain on the other side

- Ingredients

- Active ingredient:
Cilostazol

- Inactive ingredients:

Microcrystalline cellulose (Avicel PH 101), Corn starch, Croscarmellose sodium, Crospovidone (Crospovidone XL-10), Sodium lauryl sulfate, Povidone (PVP K-30), Purified water, Colloidal silicon dioxide (Aerosil 200) and Magnesium stearate

- MAL Number: -

Manufacturer

UNISON LABORATORIES CO., LTD.
39 Moo 4, Klong Udomcholjorn, Muang Chachoengsao, Chachoengsao 24000 Thailand.

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Product Registration Holder

Medispec (M) Sdn Bhd
No. 55 & 57, Lorong Sempadan 2
(Off Boundary Road),
11400 Ayer Itam, Penang, Malaysia

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