

# Cilostazol 50 mg tablets

# Cilostazol 100 mg tablets

cilostazol

**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.
- 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 effects not listed in this leaflet. See section 4.

**What is in this leaflet:**

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

## 1. WHAT CILOSTAZOL IS AND WHAT IT IS USED FOR

The active compound of Cilostazol (cilostazol) 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 Cilostazol 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. Cilostazol can increase the distance you can walk without pain since it improves the blood circulation in your legs. Cilostazol 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 CILOSTAZOL

**Do not take Cilostazol**

- 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 heart beat.
- 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 Cilostazol:

- if you have a severe heart problem or any problems with your heart beat.
- if you have problems with your blood pressure.

**During treatment with Cilostazol make sure that**

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

**Children and adolescents**

**Cilostazol is not suitable for children.**

**Other medicines and Cilostazol**

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 Cilostazol your doctor may perform some routine blood tests.

Certain medicines may interfere with the effect of Cilostazol when taken together. They may either increase the side effects of Cilostazol or make Cilostazol less effective. Cilostazol may do the same to other medicines. Before you start taking Cilostazol, 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 or simvastatin or atorvastatin (to treat high cholesterol in the blood)
- halofantrine (to treat malaria)
- pimozone (to treat mental illnesses)
- ergot derivatives (to treat migraine, e.g. ergotamine, dihydroergotamine)
- carbamazepine 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 Cilostazol, please inform your doctor if you are taking medicines for high blood pressure because Cilostazol 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 Cilostazol together and your doctor will be able to decide what is suitable for you.

**Cilostazol with food and drink**

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

Always take your tablets with a drink of water.

**Pregnancy and breast-feeding**

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.

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

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

**Driving and using machines**

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

## 3. HOW TO TAKE CILOSTAZOL

- 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 two 50 mg tablets (or 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 interfere with the effect of Cilostazol.
- Cilostazol should be taken 30 minutes before breakfast and the evening meal. Always take your tablets with a drink of water.

Some benefits of taking Cilostazol 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**

**Cilostazol is not suitable for children.**

### **If you take more Cilostazol than you should**

If for any reason you have taken more Cilostazol than you should, you may have signs and symptoms such as severe headache, diarrhoea, 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 Cilostazol**

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 Cilostazol**

If you stop taking Cilostazol the pain in your legs may come back or get worse. Therefore, you should only stop taking Cilostazol 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 Cilostazol 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 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 a 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 Cilostazol. You should tell your doctor as soon as possible:**

**Very common side effects** (may affect more than 1 in 10 people):

- headache
- abnormal stools
- diarrhoea

**Common side effects** (may affect up to 1 in 10 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** (may affect up to 1 in 100 people):

- heart attack
- irregular heart beat (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** (may affect up to 1 in 1,000 people):

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

**Not known** (frequency cannot be estimated from the available data):

- 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

### **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](http://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 CILOSTAZOL**

This medicinal product does not require any special storage conditions.

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 after "EXP". The expiry date refers to the last day of that month.

Do not use this medicine if you notice visible signs (e.g. discoloration) 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 protect the environment.

## **6. CONTENTS OF THE PACK AND OTHER INFORMATION**

### **What Cilostazol contains**

- The active substance is cilostazol. Each tablet contains 50 or 100 mg cilostazol.
- The other ingredients are microcrystalline cellulose, maize starch, carmellose calcium, hypromellose and magnesium stearate.

### **What Cilostazol looks like and contents of the pack**

Appearance:  
50 mg: Odourless or almost odourless, white or almost white, round, flat, bevelled edge tablets. The tablets are with stylized E engraving on one side and 601 code on the other side.  
100 mg: Odourless or almost odourless, white or almost white, round, flat, bevelled edge tablets. The tablets are with stylized E engraving and 602 code on one side and no sign on the other side.

Package: 28 (2x14) or 56 (4x14) tablets in PVC/PVdC/Aluminium blisters in carton box with package leaflet. Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer**

#### **Marketing Authorisation Holder:**

Consilient Health Limited,  
5th Floor, Beaux Lane House,  
Mercer Street Lower,  
Dublin 2, Ireland

#### **Manufacturer:**

Egis Pharmaceuticals PLC,  
H-1106 Budapest,  
Keresztúri út 30-38,  
Hungary

**This leaflet was last revised in September 2018.**