PACKAGE LEAFLET

Package leaflet: Information for the patient

Cilostazol 50 mg tablets
Cilostazol 100 mg tablets

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

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 (aspirin) 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.

Before taking this medicine make sure your doctor knows:
- if you have a severe heart problem or any other 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, bleeding, fever or sore throat stop taking Cilostazol and tell your doctor.

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 tell 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 (aspirin)
- clopidogrel
- anticoagulant medicines (e.g. heparin, 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 this medicine, please tell your doctor if you are taking:
- certain antibiotics (such as erythromycin, clarithromycin or rifampicin)
- medicines used to treat fungal infections (such as ketoconazole)
- medicines used to treat excess acid in the stomach (such as omeprazole)
- diltiazem (to treat high blood pressure or chest pain)
- cisapride (to treat stomach disorders)
- medicines used to treat high cholesterol in the blood (such as lovastatin, simvastatin or atorvastatin)
- halofantrine (to treat malaria)
- protease inhibitors (medicines used to treat HIV infection)
- pimozide (to treat mental illnesses)
- ergot derivatives (to treat migraine, e.g. ergotamine, dihydroergotamine)
- medicines used to treat convulsions (such as carbamazepine or phenytoin 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 tell 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.

If you smoke whilst taking cilostazol this may reduce the effect of this medicine. Stopping smoking is also recommended to help the conditions being treated (see What Cilostazol is and what it is used for).

Cilostazol with food and drink
Cilostazol tablets should be taken 30 minutes before breakfast and the evening meal, as taken at the same of the meal affects how the medicine gets into your body and may increase the risk of side effects.

If you drink large amounts of grapefruit juice with this medicine it may reduce its effect.

Pregnancy and breast-feeding
Cilostazol **MUST NOT** be used during pregnancy.
For breast-feeding mothers use of this medicine 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
Cilostazol may cause dizziness. If you feel dizzy after taking this medicine, **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 older people. However, your doctor may prescribe a lower dose if you are taking other medicines which may interfere with the effect of cilostazol.

Cilostazol 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 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 and adolescents.

If you take more Cilostazol than you should
If for any reason you have taken more Cilostazol tablets than you should, you may have signs and symptoms such as severe headache, diarrhoea, increase in heart rate, 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 this medicine 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.

Common side effects (may affect up to 1 in 10 people):
a pain or uncomfortable feeling in the chest, often spreading to the arms or neck and sometimes to the shoulders and back. This may be caused by too little blood and oxygen getting to the heart

Uncommon side effects (may affect up to 1 in 100 people):
- heart attack
- diabetes
- irregular heart beat (new or worsening) bleeding of the stomach and eyes. There may be a higher risk of bleeding into the eye in people with diabetes
- heart problems which can cause shortness of breath or ankle swelling
- increased heart rate
- pneumonia.

Rare side effects (may affect up to 1 in 1,000 people):
- Kidney failure.

Not known side effects (frequency cannot be estimated from the available data):
- stroke (which may be due to a bleed in the brain)
- bleeding of lungs, muscles, breathing passages and underneath the skin
- noticeable bleeding
- easy bruising
- serious illness with blistering of the skin, mouth, eyes and genitals or severe skin diseases which starts with painful red areas, then large blisters leading to peeling of layers of skin. This is accompanied by fever and chills, aching muscles and generally feeling unwell

- yellowing of the skin or whites of the eyes caused by liver or blood problems (jaundice)
- decrease in red cells, white cells and platelets in your blood
- severe decrease in red blood cells which may be seen in blood tests.

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):
- heart pounding (palpitation)
- dizziness
- 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):
- shortness of breath
- cough
- chills
- unexpected bleeding
- tendency to bleed (e.g., nose bleed and blood in spit or urine)
- decrease in red cells in the blood
- dizziness on standing up due to a drop in blood pressure
- fainting
- anxiety
- difficulty sleeping
- unusual dreams
- allergic reaction
- aches and pains
- increased blood sugar
- stomach ache (gastritis)
- feeling unwell.

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.

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

- changes in the blood pressure
- difficulty moving
- pain
- hot flushes
- eczema and other skin rashes
- hives
- reduced sensation of the skin
- runny or sticky eyes (conjunctivitis)
- ringing in the ears (tinnitus)
- abnormally frequent urination
- increase in blood urea, uric acid and creatinine levels which may be seen in blood tests.

Reporting side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any 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 Cilostazol

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 date of the month.

This medicine does not require any special storage conditions.

Do not throw 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
50 mg tablet: Each tablet contains 50 mg cilostazol.
100 mg tablet: Each tablet contains 100 mg cilostazol.

The other ingredients are maize starch, microcrystalline cellulose, carmellose calcium, hypromellose and magnesium stearate.

What Cilostazol looks like and contents of the pack
Each Cilostazol 50 mg tablet is a white to off-white, flat-faced, round tablets, marked with “50” on one side.
Each Cilostazol 100 mg tablet is a white to off-white, flat-faced, round tablets, marked with “100” on one side.

Cilostazol is available in blister packs of:
50 mg & 100 mg: 7, 10, 14 & 56 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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

Manufacturer

Adamed Pharma S.A.
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