

Package Leaflet: Information for the patient

Cilostazol 100mg 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, 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 side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Cilostazol 100mg Tablets are and what they are used for
2. What you need to know before you take Cilostazol 100mg Tablets
3. How to take Cilostazol 100mg Tablets
4. Possible side effects
5. How to store Cilostazol 100mg Tablets
6. Contents of the pack and other information

1. WHAT CILOSTAZOL 100MG TABLETS ARE AND WHAT THEY ARE USED FOR

Cilostazol 100mg Tablets contains the active substance Cilostazol.

Cilostazol 100mg Tablets 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 100mg Tablets 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 100mg Tablets 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 100MG TABLETS

Do not take Cilostazol 100mg Tablets:

- 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 now or previously suffered from blackouts due to heart disease, or any severe disturbances of the heartbeat;
- If you have had a heart attack or chest pain in the last 6 months or any heart problems which needed medical treatment in the last 6 months;
- If you have been told, by your doctor that you have an intolerance to some sugars;
- If you know that you have a condition which increases your risk of bleeding or bruising, such as:
 - o Active stomach ulcer(s);
 - o Stroke in the last 6 months;
 - o Problems with your eyes if you have diabetes;
 - o 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 100mg Tablets:

- If you have a severe heart problem or problems with your heartbeat;
- If you have problems with your blood pressure;

During treatment with Cilostazol 100mg Tablets make sure that;

- If you need to have surgery including having teeth removed, tell your doctor or dentist that you are taking Cilostazol 100mg Tablets;
- If you experience easy bruising or bleeding, stop taking Cilostazol 100mg Tablets and tell your doctor.

Children and adolescents

Cilostazol 100mg Tablets 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 the muscles or joints, or if you take medicines to reduce blood clotting. These medicines include:

- Acetylsalicylic acid (aspirin);
- Clopidogrel;
- Anticoagulant medicines (e.g. warfarin, dabigatran, rivaroxaban, apixaban or low molecular weight heparins).

If you are taking such medicines with Cilostazol 100mg Tablets your doctor may perform some routine blood tests.

Certain medicines may interfere with the action of Cilostazol 100mg Tablets if they are taken together. They may either increase the side effects of Cilostazol 100mg Tablets or make Cilostazol 100mg Tablets less effective. Cilostazol 100mg Tablets may do the same to other medicines. Before you start taking Cilostazol 100mg Tablets, please tell your doctor if you are taking:

- Erythromycin, clarithromycin or rifampicin (antibiotics);
- Ketoconazole (to treat fungal infections);
- Omeprazole (to treat excess stomach acid);

- 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 illness);
- 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 100mg Tablets, please inform your doctor if you are taking medicines for high blood pressure or any other medicines which can lower your blood pressure because Cilostazol 100mg Tablets may have an additional lowering effect on your blood pressure. If your blood pressure falls too low, this could cause a fast heartbeat.

It may still be all right for you to take the above mentioned medicines and Cilostazol 100mg Tablets together. Your doctor will be able to decide what is suitable for you.

Cilostazol 100mg Tablets with food and drink

Cilostazol 100mg Tablets should be taken 30 minutes before breakfast and the evening meal. Always take your tablets with a drink of water.

Talk to your doctor before drinking grapefruit juice while taking this medicine

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 100mg Tablets **MUST NOT** be used during pregnancy

For breast-feeding mothers use of Cilostazol 100mg Tablets is **NOT RECOMMENDED**.

Driving and using machines

Cilostazol 100mg Tablets may cause dizziness. If you feel dizzy after taking Cilostazol 100mg Tablets DO NOT drive and do not use any tools or machines and inform your doctor or pharmacist.

Cilostazol 100mg Tablets contains Sorbitol (E420)

- If you have been told, by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE CILOSTAZOL 100MG TABLETS

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 100mg 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 Cilostazol 100mg Tablets.

Cilostazol 100mg 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 100mg Tablets 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 100mg Tablets is not suitable for children.

If you take more Cilostazol 100mg Tablets than you should

If for any reason you have taken more Cilostazol 100mg Tablets 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 100mg Tablets

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 the forgotten tablet.

If you stop taking Cilostazol 100mg Tablets

If you stop taking Cilostazol 100mg Tablets the pain in your legs may come back or get worse. Therefore, you should only stop taking Cilostazol 100mg Tablets 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 100mg Tablets and contact your doctor or go to the nearest hospital immediately:

Common (may affect up to 1 in 10 people)

- Easy bruising;
- Irregular heartbeat (new or getting worse);

Uncommon (may affect up to 1 in 100 people)

- Heart attack;
- Heart problems, which cause shortness of breath and ankle swelling;
- Unexpected bleeding – uncommon; may affect up to 1 in 100 people;
- Tendency to bleed (e.g. of the stomach, eye or muscle, nose bleed and blood in spit or urine).

There may be a higher risk of bleeding in the eye in people with diabetes. Signs and symptoms of bleeding can include (but not limited to): vomiting blood, black/dark stools, bloody stools, abdominal pain and pale skin

Not known (Frequency cannot be estimated from available data)

- Stroke;
- Noticeable bleeding;
- Serious illness with blistering of the skin, mouth, eyes and genitals;
- Yellowing of the skin or the whites of the eyes caused by liver or blood problems (jaundice);

- Liver problems, including hepatitis (inflammation of the liver); symptoms include (but not limited to): abdominal pain, dark urine, pale stools and loss of appetite;
- Allergic reactions including severe reactions such as eczema, skin eruptions, Steven-Johnsons syndrome, toxic epidermal necrolysis (a life threatening allergic reaction) and/or hives (known as urticaria);
- Sore throat or fever. You may need to have some blood tests and your doctor will decide on your further treatment;
- Ringing in the ears (tinnitus);
- Changes in the urine (e.g. presence of blood);
- Symptoms of mouth ulcers, tiredness, feeling weak, unexplained bruising or bleeding. These symptoms are a sign of agranulocytosis and a reduced blood count;

Other side effects

The following side effects have been reported for cilostazol. You should tell your doctor as soon as possible if you experience any of them:

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

- Headache;
- Abnormal stools;
- Diarrhoea.

Common (may affect up to 1 in 10 people):

- Fast heartbeat;
- Heart pounding (palpitations);
- Chest pain;
- 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 the ankles, feet or face;
- Rash or changes in the appearance of the skin;
- Itchy skin;
- Patchy bleeding in the skin;
- General weakness.

Uncommon (may affect up to 1 in 100 people):

- Pneumonia;
- Cough;
- Chills;
- Decrease in red cells in the blood;
- Dizziness on standing up;
- Fainting;
- Anxiety;
- Difficulty sleeping;
- Unusual dreams;
- Aches and pains;
- Diabetes and increased blood sugar;
- Stomach ache (gastritis);
- Difficulty breathing;

- Malaise.

Rare (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 available data)

- Changes in the blood pressure;
- Decrease in the red cells, white cells and platelets in the blood;
- Difficulty moving;
- Hot flushes;
- Reduced sensation of the skin;
- Runny or sticky eyes (conjunctivitis);
- Increase in levels of certain substances in your body. Your doctor will monitor your blood regularly
- Symptoms of prolonged cough or difficulty breathing, fever and feeling generally unwell. These symptoms could be a sign of interstitial pneumonia.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via

HPRA Pharmacovigilance

Earlsfort Terrace

IRL - Dublin 2

Tel: +353 1 6764971

Fax: +353 1 6762517

Website: www.hpra.ie

e-mail: medsafety@hpra.ie

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

5. HOW TO STORE CILOSTAZOL 100MG TABLETS

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

Do not store above 25°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 carton. The expiry date refers to the last day of that month.

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 100mg Tablets contains

The active substance is cilostazol. Each tablet contains 100mg cilostazol.

The other ingredients are sorbitol (E420), talc, microcrystalline cellulose, crospovidone A, calcium carmellose, colloidal silica anhydrous, magnesium stearate and stearic acid.

What Cilostazol 100mg Tablets look like and contents of the pack

The tablets are white or almost white, round and flat.

Each pack contains 56 tablets.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation Holder is:

Focus Pharmaceuticals Limited, Capital House, 85 King William Street, London EC4N 7BL, UK

The Manufacturer is:

Normon S.A., Ronda de Valdecarrizo, 6-28760 Tres Cantos, Madrid, Spain.

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