Dispense with Patient Information available at: www.puracaplabs.com/patientinfo/Cilostazol-Tablet.pdf

PATIENT INFORMATION

Cilostazol (sye loe' sta zol)

Tablets, for oral use

Read this Patient Information leaflet before you start taking cilostazol and each time you get a refill. There may be new information. This information does not take the place of talking to your doctor about your medical condition or your treatment.

What is the most important information I should know about cilostazol? Cilostazol can cause serious side effects:

• Cilostazol stops a protein called phosphodiesterase III from working. Other similar drugs which affect this protein may cause death if you already have heart problems, called class 3 to 4 (III-IV) heart failure. **Do not** take cilostazol if you have heart failure of any kind.

What is cilostazol?

Cilostazol is a prescription medicine used to reduce the symptoms of intermittent claudication and can increase your ability to walk further distances.

It is not known if cilostazol is safe and effective for use in children.

How does cilostazol work?

Improvement in symptoms may occur as soon as 2 weeks, but could take up to 12 weeks.

Who should not take cilostazol?

Do not take cilostazol if you:

- have heart problems (heart failure)
- are allergic to cilostazol or any of the ingredients in cilostazol. See the end of this leaflet for a complete list of ingredients in cilostazol.

Tell your doctor before taking this medicine if you have any of these conditions.

What should I tell my doctor before taking cilostazol?

Before you take cilostazol, tell your doctor if you:

- drink grapefruit juice. Taking cilostazol and drinking grapefruit juice can increase the amount of cilostazol causing side effects.
- have any other medical conditions.
- are pregnant or planning to become pregnant. It is not known if cilostazol will harm your unborn baby.
- are breastfeeding or planning to breastfeed. It is not known if cilostazol passes into your breast milk. You and your doctor should decide if you will take cilostazol or breastfeed. You should not do both.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins and herbal supplements.

Ask your doctor for a list of these medicines if you are not sure. You can ask your pharmacist for a list of medicines that interact with cilostazol. Know the medicines you take. Keep a list of them to show to your doctor and pharmacist when you get a new medicine.

How should I take cilostazol?

- Take cilostazol exactly as your doctor tells you to take it.
- Your doctor will tell you how much cilostazol to take and when to take it.
- Your doctor may change your dose if needed.
- Take cilostazol 30 minutes before you eat or 2 hours after you eat.

What are the possible side effects of cilostazol?

Cilostazol may cause serious side effects, including:

- heart problems. Taking cilostazol may cause you to have heart problems, including a fast heart beat, palpitations, irregular heartbeat, and low blood pressure.
- See "What is the most important information I should know about cilostazol?"

- severe allergic reactions (anaphylaxis, angioedema). Call your doctor or go to the nearest emergency room right away if you have any of the following signs or symptoms of a severe allergic reaction:
 - \circ hives
 - \circ swelling of your face, lips, mouth, or tongue
 - trouble breathing or wheezing
 - dizziness
- changes in your blood cell counts (thrombocytopenia or leukopenia). Your doctor should do blood tests to check your blood cell counts while you take cilostazol.

The most common side effects of cilostazol include:

- headache
- abnormal stools
- diarrhea

Tell your doctor if you have any side effect that bothers you or does not go away. These are not all the possible side effects of cilostazol. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store cilostazol?

Store cilostazol at room temperature between 68°F to 77°F (20°C to 25°C).

Keep cilostazol and all medicines out of the reach of children.

General information about the safe and effective use of cilostazol.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use cilostazol for a condition for which it was not prescribed. Do not give cilostazol to other people, even if they have the same symptoms that you have. It may harm them.

This Patient Information summarizes the most important information about cilostazol. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about cilostazol that is written for health professionals.

What are the ingredients in cilostazol?

Active ingredient: cilostazol

Inactive ingredients: carboxymethylcellulose calcium, corn starch, hypromellose, magnesium stearate, microcrystalline cellulose

This Patient Information has been approved by the U.S. Food and Drug Administration.

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