

# PLETAL<sup>®</sup>

Cilostazol (*sil-OS-tah-zol*)

## Consumer Medicine Information

### What is in this leaflet

Please read this leaflet carefully before you start using PLETAL.

This leaflet answers some common questions about PLETAL.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking PLETAL against the benefits they expect it will have for you.

**If you have any concerns about taking this medicine, ask your doctor or pharmacist.**

**Keep this leaflet with the medicine.**

You may need to read it again.

### What PLETAL is used for

PLETAL is used to treat intermittent claudication. Blockage of the blood vessels to the legs, causes a distinctive type of pain called intermittent claudication. In this condition, which usually affects the calves, you experience muscle pain or cramping whenever you walk some distance, but the pain disappears when you rest. The pain occurs because the calf muscles are not receiving enough oxygen.

PLETAL 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.

PLETAL belongs to a group of medicines called phosphodiesterase inhibitors.

This medicine works by preventing blood clots and widening blood vessels.

**Ask your doctor if you have any questions about why this medicine has been prescribed for you.**

Your doctor may have prescribed it for another reason.

This medicine is available only with a doctor's prescription.

There is not enough information to recommend the use of this medicine for children under the age of 18 years.

### Before you take PLETAL

**When you must not take it**

**Do not take PLETAL if you have an allergy to:**

- any medicine containing cilostazol
- any of the ingredients listed at the end of this leaflet
- any other similar medicines (such as medicines of the same class).

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body

- rash, itching or hives on the skin

**Do not take this medicine if you are pregnant.**

It may affect your developing baby if you take it during pregnancy. If you become pregnant while taking this medicine, tell your doctor immediately.

**Do not breast-feed if you are taking this medicine.**

The active ingredient in PLETAL passes into breast milk and there is a possibility that your baby may be affected.

**Do not take this medicine if you have any of the following conditions:**

- heart failure
- unusual heart beat
- bleeding tendency
- moderate, or severe liver problems
- severe kidney problems

**Do not take this medicine if you are taking two or more medicines used to prevent blood clots such as warfarin, heparin, aspirin, clopidogrel, dabigatran, rivaroxaban, or apixaban.**

**Do not take this medicine if you are taking medicines used to:**

- **treat high blood pressure such as diltiazem**
- **treat peptic ulcer such as cimetidine, lansoprazole, or omeprazole**
- **treat infections such as erythromycin, ketoconazole,**
- **treat HIV such as lopinavir, ritonavir, tripranovir or indinavir**

**Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.**

If it has expired or is damaged, return it to your pharmacist for disposal.

**If you are not sure whether you should start taking this medicine, talk to your doctor.**

### ***Before you start to take it***

**Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.**

**Tell your doctor if you have or have had any of the following medical conditions:**

- stomach ulcer
- diabetes
- high blood pressure
- damage to the brain in the past 6 months
- surgery in the past 3 months
- persistent chest pain at rest
- heart attack or heart surgery in the last six months

**If you have not told your doctor about any of the above, tell him/her before you start taking PLETAL.**

### ***Taking other medicines***

**Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.**

Some medicines and PLETAL may interfere with each other.

These include:

- medicines used to treat infection such as erythromycin or ketoconazole
- medicines used to treat high cholesterol levels such as simvastatin or atorvastatin

These medicines may be affected by PLETAL or may affect how well it works. You may need different

amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

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## **How to take PLETAL**

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**Follow all directions given to you by your doctor or pharmacist carefully.**

They may differ from the information contained in this leaflet.

**If you do not understand the instructions on the box, ask your doctor or pharmacist for help.**

### ***How much to take***

The usual dose is 100 mg taken two times each day.

**Ask your doctor or pharmacist if you are unsure of the correct dose for you.**

They will tell you exactly how much to take.

**Follow the instructions they give you.**

If you take the wrong dose, PLETAL may not work as well and your problem may not improve.

### ***How to take it***

**Swallow the tablets whole with a full glass of water.**

### ***When to take it***

Pletal tablets should be taken 30 minutes before or two hours after breakfast and the evening meal.

**Take your medicine at about the same time each day.**

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

### ***How long to take it***

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.

**Continue taking your medicine for as long as your doctor tells you.**

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

### ***If you forget to take it***

**If it is less than 6 hours before your next dose, skip the dose you missed and take your next dose when you are meant to.**

**Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.**

**Do not take a double dose to make up for the dose that you missed.**

This may increase the chance of you getting an unwanted side effect.

**If you are not sure what to do, ask your doctor or pharmacist.**

**If you have trouble remembering to take your medicine, ask your pharmacist for some hints.**

### ***If you take too much (overdose)***

**Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much PLETAL. Do this even if there are no signs of discomfort or poisoning.**

You may need urgent medical attention.

Symptoms of an overdose may include:

- diarrhoea
- severe headache
- unusual heartbeat

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## While you are using PLETAL

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### **Things you must do**

**If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking PLETAL.**

**Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.**

**If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.**

It may affect other medicines used during surgery.

**If you become pregnant while taking this medicine, tell your doctor immediately.**

**If you are about to have any blood tests, tell your doctor that you are taking this medicine.**

It may interfere with the results of some tests.

**Keep all of your doctor's appointments so that your progress can be checked.**

Your doctor may do some tests (blood test, clotting test, echocardiogram of the heart) from time to time to make sure the medicine is working and to prevent unwanted side effects.

### **Things you must not do**

**Do not take PLETAL to treat any other complaints unless your doctor tells you to.**

**Do not give your medicine to anyone else, even if they have the same condition as you.**

**Do not stop taking your medicine or lower the dosage without checking with your doctor.**

If you stop taking it suddenly, your condition may worsen or you may have unwanted side effects from other medicines you are taking. If possible, your doctor will gradually reduce the amount you take each day before stopping the medicine completely.

### **Things to be careful of**

**Be careful driving or operating machinery until you know how PLETAL affects you.**

This medicine may cause dizziness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

**If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.**

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

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## Side effects

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**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking PLETAL.**

This medicine helps most people with intermittent claudication, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

**Do not be alarmed by the following lists of side effects. You may not experience any of them.**

**Ask your doctor or pharmacist to answer any questions you may have.**

**Tell your doctor or pharmacist if you notice any of the following and they worry you:**

- unusual heart beat
- headache or dizziness
- diarrhoea or constipation
- dyspepsia, nausea or vomiting
- increased thirst and/or hunger
- increased urination
- inability to sleep
- abnormal dreams

- anxiety
- rash
- muscle pain
- swelling of the feet, hands or face

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

**Tell your doctor as soon as possible if you notice any of the following:**

- persistent bleeding (e.g. nose bleeds)
- easy bruising
- black or abnormal stools

The above list includes serious side effects that may require medical attention. Serious side effects are rare.

**If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:**

- frequent infections, sore throat, severe chills or fever
- bleeding excessively
- tiredness, looking pale with headaches or dizziness
- unusual heart beat
- chest pain or discomfort

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

**Tell your doctor or pharmacist if you notice anything that is making you feel unwell.**

Other side effects not listed above may also occur in some people.

Some of these side effects can only be found when your doctor does tests from time to time to check your progress.

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## After using PLETAL

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### **Storage**

**Keep your tablets in the pack until it is time to take them.**

**If you take the tablets out of the pack they may not keep well.**

**Keep your tablets in a cool dry place where the temperature stays below 25C.**

**Do not store PLETAL or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.**

Heat and dampness can destroy some medicines.

**Keep it where children cannot reach it.**

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

### ***Disposal***

**If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.**

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## **Product description**

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### ***What it looks like***

50 mg tablet (not currently marketed)

White, round, flat faced tablets debossed with "OG31" on one side.

100 mg tablet

White, round, flat faced tablets debossed with "OG30" on one side.

Pletal tablets are available in blister packs of 56 tablets.

### ***Ingredients***

PLETAL contains cilostazol as the active ingredient.

It also contains:

- starch - maize
- microcrystalline cellulose
- carmellose calcium
- hypromellose
- magnesium stearate

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

### ***Distributor***

PLETAL is distributed in Australia by:

Otsuka Australia Pharmaceutical Pty Ltd

Suite 2.03, Level 2

9 Help Street

Chatswood NSW 2067

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This leaflet was revised in December 2017

50 mg tablet AUST R 140598

100 mg tablet AUST R 140599