

PLETAAL TABLETS

Cilostazol (50mg, 100mg)

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What PLETAAL is used for

PLETAAL is used to treat intermittent claudication, a distinctive type of pain at the legs. It is usually caused by blockage of the blood vessels to the leg, hence the calf muscles are not receiving enough oxygen. The muscle pain or cramping happen whenever you walk some distance but the pain disappears when you rest. Pletaal only works if there is no peripheral tissue death.

It is also used for prevention of recurrence of cerebral infarction (lack of oxygen supply to brain tissue), excluding cardiogenic cerebral embolism (an obstruction in brain artery by a plaque or blood clot which originates from the heart).

How PLETAAL works

PLETAAL inhibit platelet aggregation and hence inhibit the formation of blood clot or plaque that causing blockage in blood vessels.

PLETAAL increases blood flow in the occluded ankle, lower limbs and brain by dilating the blood vessels and hence to improve the blood circulation.

Before you use PLETAAL

- When you must not use it

You must not take PLETAAL if you are:

- With congestive heart failure of any severity
- With haemostatic disorders or active pathologic bleeding such as bleeding stomach ulcer and intracranial (bleeding in the brain)
- Sensitive to any PLETAAL's components.

- Before you start to use it

- Please consult your doctor before starting therapy and whenever therapy is renewed in case the information has changed.
- Take PLETAAL at least half hour before food or two hours after food.
- The relief of pain may not be immediate. Although you may experience pain relief in 2 to 4 weeks after the initial therapy, treatment up to 12 weeks may be required before the beneficial effect is experienced.
- Please take note that there may be uncertain cardiovascular risk when used long-term or if you have severe underlying heart disease

Please tell your doctor or pharmacist if you are:

- Having or have had any heart problem, especially heart failure
- Considering any surgery or pathologic process
- Having or have had thrombocytopenia (reduction in blood platelets, which increases risk of bleeding or bruising)
- Having or have had severe

liver impairment

- Having or have had severe kidney impairment
- Pregnant or nursing a child.

- Taking other medicines

Please inform your doctor or pharmacist if you are taking any prescribed or non-prescription medicines, especially:

- Other antiplatelet or anticoagulant agents(e.g. acetylsalicylic acid, clopidogrel, heparin, warfarin, acenocoumarol, dabigatran, rivaroxaban or apixaban) for increased potential risk of bleeding
- Itraconazole, erythromycin, diltiazem, ketoconazole, omeprazole, quinidine as these drugs might slow the metabolism of PLETAAL.

How to use PLETAAL

- How much to use

The recommended dosage of PLETAAL is 100mg twice daily taken at least half an hour before or two hours after breakfast and dinner. A dose of 50mg twice daily may be given by your doctor if you are taking some medicines concomitantly.

- When to use it

PLETAAL should be taken twice daily at least half an hour before or two hours after breakfast and dinner.

- How long to use it

You may start to feel the effect as early as 2 to 4 weeks after the initiation of therapy, but treatment for up to 12 weeks may be needed before a

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beneficial effect is experience.

Your doctor may need to reassess you after 3 months of treatment with a view to discontinuing PLETAAL if an inadequate effect is observed or symptoms have not been improved.

- *If you forget to use it*

If you miss a dose, take the dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and follow your regular dosing schedule. You should never take two doses at one time.

- *If you use too much (overdose)*

If you or anyone accidentally consumed too much PLETAAL, please go to your nearest hospital for treatment as you may need medical assistance. Some of the signs of PLETAAL overdose are: severe headache, diarrhea, hypotension (low blood pressure), tachycardia (unusual heart beat), and possibly cardiac arrhythmias (irregular heart beat).

While you are using it

- *Things you must do*

Take PLETAAL as prescribed by your doctor.

- *Things you must not do*

- Do not use after the expiry date. Please refer to the outer label for the expiry date.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- Do not breastfeed a baby if you are taking PLETAAL.

- *Things to be careful of*

- Some patients have reported dizziness or vertigo while on PLETAAL, hence, do not drive or operate machinery until you know how it affects you.
- Please take note that a high-fat meal will increase absorption of PLETAAL.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking PLETAAL. Some of the reported side effects are:

Nervous System Disorders: Headache, Dizziness

Gastrointestinal disorders: Diarrhea, Dyspepsia

Infections and infestations: Interstitial pneumonia (inflammation of the lungs which cause breathlessness, cough and raised temperature)

Blood and lymphatic system disorders: Agranulocytosis (severe reduction in number of white blood cells which makes infections more likely), Anaemia (reduction in red blood cells which can make the skin pale and cause weakness or

breathlessness), Bleeding tendency, Granulocytopenia or Leukopenia (abnormally low number of granular cells or white blood cells), Pancytopenia (severe reduction in blood cells which can cause weakness, bruising or infection more likely), Thrombocytopenia (reduction in blood platelets, which increases risk of bleeding or bruising)

Metabolism and nutrition disorders: Anorexia (loss of appetite)

Psychiatric disorders: Insomnia (difficulty in sleeping)

Nervous system disorders: Cerebral haemorrhage (bleeding in brain)

Eye disorders: Conjunctivitis, Retinal haemorrhage (bleeding in eye)

Ear and labyrinth disorders: Tinnitus (ringing in the ears)

Cardiac disorders: Palpitation (fast, hard and rapid heartbeat), Tachycardia (fast heart beat), Angina pectoris (chest pain), Atrial fibrillation (a disorder of the heart beat associated with a higher risk of stroke), Congestive heart failure (a condition in which the heart cannot pump enough of blood to supply the body's tissues with sufficient oxygen and nutrients; back up of blood in vessels and the lungs causes build-up of fluid in the tissues), Myocardial infarction (heart attack), Supraventricular tachycardia (faster heart beat that originates above the ventricles), Ventricular extrasystoles (a premature beat arising from the ventricle), Ventricular tachycardia (faster heart beat that originates from one of the lower chambers of the heart)

Vascular disorders: Hot flushes, Hypertension (high blood pressure), Hypotension (low blood pressure)

Respiratory, thoracic and mediastinal disorders:

Epistaxis (nose bleed), Pulmonary haemorrhage (bleeding in lungs)

Gastrointestinal disorders: Dyspepsia (painful, disturbed or difficult digestion), Flatulence, Nausea, Abdominal pain, Gastrointestinal haemorrhage (bleeding in the gastrointestinal tract), Melena (the passage of dark stools stained with altered blood), Vomiting

Hepatobiliary disorders: Hepatic function abnormal (abnormal liver function), Jaundice (yellowing of the skin or whites of the eyes caused by liver or blood problems)

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Skin & subcutaneous tissue disorders: Haemorrhage subcutaneous (bleeding under the skin), Pruritus (itching), Rash, Skin drug eruptions (any skin eruption induced by injection, inhalation or ingestion of a drug, usually as the result of allergic sensitization), Urticaria (raised, itchy rash that appears on the skin)

General disorders and administration site conditions: Peripheral edema (accumulation of interstitial fluid in lower limbs), Chest pain, Oedema generalized, Malaise, Pain

Renal and urinary disorders: Hematuria (the presence of blood in urine), Pollakiuria (abnormally frequent passage of urine)

Investigations: Blood creatinine increased, Blood pressure decreased, Blood pressure increased, Blood urea increased, Blood uric acid increased, Platelet count decreased, White blood cell count decreased.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting).

Storage and Disposal of PLETAAL

- Storage

Store below 30°C.

- 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.

Product Description

- What it looks like

PLETAAL tablets are white compressed tablets.

- Ingredients

Active ingredient

Cilostazol

Inactive ingredients

PLETAAL 50MG TABLETS:

Carboxymethyl Cellulose
Calcium, Corn Starch,
Microcrystalline Cellulose,
Hydroxypropyl Methyl
Cellulose 2910, Magnesium
Stearate

PLETAAL 100MG

TABLETS: Carboxymethyl
Cellulose Calcium, Corn
Starch, Microcrystalline
Cellulose, Hydroxypropyl
Methyl Cellulose 2910,
Magnesium Stearate,

MAL numbers:

PLETAAL 50MG TABLETS:

MAL20061476A

PLETAAL 100MG

TABLETS: MAL20061475A

Manufacturer

Korea Otsuka Pharmaceutical
Co Ltd
27, Jeyakongdan 3-gil,
Hyangnam-eup, Hwaseong-si,
Gyeonggi-do, Korea.

Product Registration Holder

A. Menarini Singapore Pte.
Ltd. (994247-T)
Level 2, No. 10, Jalan Bersatu
13/4,
46200 Petaling Jaya,
Selangor, Malaysia.

Date of revision

29/07/2015