

PACKAGE LEAFLET: INFORMATION FOR THE USER

Pletal® 50 mg 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.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Pletal is and what it is used for
2. Before you take Pletal
3. How to use Pletal
4. Possible side effects
5. How to store Pletal
6. Contents of the pack and other information

1. WHAT PLETAL IS AND WHAT IT IS USED FOR

Pletal 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 vessels called platelets inside your vessels.

You have been prescribed Pletal 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. Pletal can increase the distance you can walk without pain since it improves 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. BEFORE YOU TAKE PLETAL

Do not take Pletal

- if you are allergic (hypersensitive) to cilostazol or any of the other ingredients of Pletal.
- 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 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

Take special care with Pletal

Before taking Pletal make sure your doctor knows:

- if you have a severe heart problem or any problems with your heart beat.
- if you have problems with your blood pressure.

During treatment with Pletal make sure that

- if you need to have surgery including having teeth removed, tell your doctor or dentist that you are taking Pletal.
- if you experience easy bruising or bleeding, stop taking Pletal and tell your doctor.

Taking other medicines

Before you start taking Pletal please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines without a prescription.

You should specifically inform 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
- clopidogrel
- anticoagulant medicines (e.g. warfarin, dabigatran, rivaroxaban, apixabam or low molecular weight heparins).

If you are taking such medicines with Pletal your doctor may perform some routine blood tests.

Certain medicines may interfere with the effect of Pletal when taken together. They may either increase the side effects of Pletal or make Pletal less effective. Pletal may do the same to other medicines. Before you start taking Pletal, please tell your doctor if you are taking:

- erythromycin, clarithromycin or rifampicin (antibiotics)
- ketoconazole (to treat fungal infections)
- omeprazole (to treat excess acid in the stomach)
- 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 illnesses)
- ergot derivatives (to treat migraine, e.g. ergotamine, dihydroergatime)
- 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 Pletal, please inform your doctor if you are taking medicines for high blood pressure because Pletal 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 Pletal together and your doctor will be able to decide what is suitable for you.

Taking Pletal with food and drink

Pletal tablets should be taken 30 minutes before breakfast and the evening meal.

Always take your tablets with a drink of water.

Pregnancy and breast-feeding

Pletal **MUST NOT** be used during pregnancy.

For breast-feeding mothers use of Pletal is **NOT RECOMMENDED**.

If you are pregnant, think you may be pregnant or if you are breast-feeding ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Pletal may cause dizziness. If you feel dizzy after taking Pletal tablets, **DO NOT** drive and do not use any tools or machines and inform your doctor or pharmacist.

3. HOW TO USE TAKE PLETAL

- Always take Pletal exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.
- The usual dose is two 50 mg tablets 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 Pletal
- Pletal 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 Pletal 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.

Pletal is not suitable for children.

If you take more Pletal than you should

If for any reason you have taken more Pletal 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 medicines you have taken.

If you forget to take Pletal

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 Pletal

If you stop taking Pletal the pain in your legs may come back or get worse. Therefore, you should only stop taking Pletal if you notice side effects requiring urgent medical attention (see section 4) or if your doctor tells you to.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Pletal 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 Pletal and contact a doctor or go to the nearest hospital immediately.

- stroke
- heart attack
- heart problems which can cause shortness of breath or ankle swelling
- irregular heart beat (new or worsening)
- noticeable bleeding
- easy bruising
- serious illness with blistering of the skin, mouth, eyes and genitals
- yellowing of the skin or whites of the eyes caused by liver or blood problems (jaundice)

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 Pletal. You should tell your doctor as soon as possible:

Very common side effects (affecting more than 1 in 10 people)

- headache
- abnormal stools
- diarrhoea

Common side effects (affecting less than 1 in 10, but more than 1 in 100 people)

- fast heart beat
- heart pounding (palpitation)
- chest pain
- dizziness
- sore throat
- 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, foot or face
- rash or changes in appearance of the skin
- itchy skin
- patchy bleeding in the skin
- general weakness

Uncommon side effects (affecting less than 1 in 100, but more than 1 in 1,000 people)

- heart attack
- irregular heart beat (new or worsening)
- heart problems that can cause shortness of breath or ankle swelling
- pneumonia
- cough
- chills
- unexpected bleeding
- tendency to bleed (e.g., of the stomach, eye or muscle, nose bleed and blood in spit or urine)
- decrease in red cells in the blood
- dizziness on standing up
- fainting
- anxiety
- difficulty sleeping
- unusual dreams
- allergic reaction
- aches and pains
- diabetes and increased blood sugar
- stomach ache (gastritis)
- malaise

There may be a higher risk of bleeding into the eye in people with diabetes.

Rare side effects (affecting less than 1 in 1,000, but more than 1 in 10,000 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 Pletal but it is known how frequently they may occur:

- changes in the blood pressure
- decrease in red cells, white cells and platelets in your blood
- difficulty breathing
- difficulty moving
- fever
- hot flushes
- eczema and other skin rashes
- reduced sensation of the skin
- runny or sticky eyes (conjunctivitis)
- ringing in the ears (tinnitus)
- liver problems including hepatitis
- changes in the urine

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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 the Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard.

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

5. HOW TO STORE PLETAL

Keep Pletal out of the sight and reach of children.

Do not use Pletal 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.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Pletal contains

The active substance is cilostazol. One tablet contains 50 mg cilostazol. The other ingredients are corn starch, microcrystalline cellulose, carmellose calcium, hypromellose and magnesium stearate.

What Pletal looks like and contents of the pack

The Pletal 50 mg tablet is a round white tablet with "OG31" engraved on one side and plain on the reverse.

Available in blister packs containing 56 Tablets.

Manufactured by Anderson Brecon (UK) Ltd., Wye Valley Business Park, Brecon Road, Hay-on-Wye, Hereford, HR3 5PG, United Kingdom and procured from within the EU and repackaged in the UK by the Product Licence holder: CD Pharma Ltd, Unit 3, Manor Point, Manor Way, Borehamwood, Herts WD6 1EE.

Pletal 50 mg Tablets

PL: 20492/0541

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Pletal is a registered trademark.

Date of preparation: 25th November 2016

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Cilostazol 50 mg Tablets

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1. WHAT CILOSTAZOL IS AND WHAT IT IS USED FOR

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2. BEFORE YOU TAKE CILOSTAZOL

Do not take Cilostazol

- if you are allergic (hypersensitive) to cilostazol or any of the other ingredients of Cilostazol.
- 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 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

Take special care with Cilostazol

Before taking Cilostazol make sure your doctor knows:

- if you have a severe heart problem or any 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 or bleeding, stop taking Cilostazol and tell your doctor.

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Before you start taking Cilostazol please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines without a prescription.

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Before you start taking Cilostazol, please tell your doctor if you are taking:

- erythromycin, clarithromycin or rifampicin (antibiotics)
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- halofantrine (to treat malaria)
- pimozide (to treat mental illnesses)
- ergot derivatives (to treat migraine, e.g. ergotamine, dihydroergatime)
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If you are not sure if this applies to your medicines ask your doctor or pharmacist.

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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.

Taking Cilostazol with food and drink

Cilostazol tablets should be taken 30 minutes before breakfast and the evening meal.

Always take your tablets with a drink of water.

Pregnancy and breast-feeding

Cilostazol **MUST NOT** be used during pregnancy.

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

If you are pregnant, think you may be pregnant or if you are breast-feeding ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

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

3. HOW TO USE TAKE CILOSTAZOL

- Always take Cilostazol exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.
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Cilostazol is not suitable for children.

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, a fall in blood pressure and irregularities of your heartbeat.

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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.

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4. POSSIBLE SIDE EFFECTS

Like all medicines, Cilostazol 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.

- stroke
- heart attack
- heart problems which can cause shortness of breath or ankle swelling
- irregular heart beat (new or worsening)
- noticeable bleeding
- easy bruising
- serious illness with blistering of the skin, mouth, eyes and genitals
- yellowing of the skin or whites of the eyes caused by liver or blood problems (jaundice)

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 (affecting more than 1 in 10 people)

- headache
- abnormal stools
- diarrhoea

Common side effects (affecting less than 1 in 10, but more than 1 in 100 people)

- fast heart beat
- heart pounding (palpitation)
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Uncommon side effects (affecting less than 1 in 100, but more than 1 in 1,000 people)

- heart attack
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- pneumonia
- cough
- chills
- unexpected bleeding
- tendency to bleed (e.g., of the stomach, eye or muscle, nose bleed and blood in spit or urine)
- decrease in red cells in the blood
- dizziness on standing up
- fainting
- anxiety
- difficulty sleeping
- unusual dreams
- allergic reaction
- aches and pains
- diabetes and increased blood sugar
- stomach ache (gastritis)
- malaise

There may be a higher risk of bleeding into the eye in people with diabetes.

Rare side effects (affecting less than 1 in 1,000, but more than 1 in 10,000 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 known how frequently they may occur:

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Cilostazol 50 mg Tablets

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