

Cardioplén® XL 2.5 mg, 5 mg & 10 mg Prolonged Release Tablets

Felodipine

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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What Cardioplén is and what it is used for

Cardioplén XL Prolonged Release Tablets contain felodipine which belongs to a group of medicines called calcium-channel blockers that act on the cardiovascular system (the heart and blood vessels). Cardioplén has been prescribed by your doctor to treat your high blood pressure or to reduce the frequency of your anginal attacks. They are called prolonged release tablets because they are manufactured in a way that allows the felodipine to be released and slowly absorbed by your body over a period of several hours.

In high blood pressure, felodipine works by widening the blood vessels. This creates less resistance to the blood flow, and results in lower blood pressure, which in turn reduces the strain on your heart.

In angina, felodipine works by opening up the arteries supplying the heart muscle and this allows more blood and oxygen to reach the muscle, decreasing the chances of angina (chest pains) occurring when extra strain is placed upon the heart.

2. What you need to know before you take Cardioplén

Do not take Cardioplén:

- if you are allergic to felodipine, other calcium-channel blockers (e.g. amlodipine, nisoldipine or nifedipine) or any of the other ingredients in Cardioplén (listed in section 6)
- if you are pregnant or likely to become pregnant
- if you have been told that you have a narrowing of the aortic valve in your heart
- if you have experienced a collapse which was caused by a heart problem
- if the severity or frequency of your angina has rapidly worsened over a matter of hours or days
- if you have had a heart attack during the last month or have other severe heart problems
- if you suffer from uncompensated heart failure.

Warnings and precautions

Talk to your doctor or pharmacist before taking Cardioplén if:

- you suffer from low blood pressure with abnormal rapid heartbeats. Symptoms of excessive low blood pressure and inadequate blood supply to the heart itself frequently include dizziness and chest pain. If you experience these symptoms, seek emergency care immediately
- you have a poorly functioning left ventricle of your heart
- you suffer from liver problems
- your gums are swollen. Practice good oral hygiene to help avoid your gums from swelling (see section 4).

Other medicines and Cardioplén

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. If you have to go to a doctor, dentist or hospital for any reason, tell them that you are taking Cardioplén. This is especially important if you are likely to have an anaesthetic or an operation.

In particular, tell your doctor if you are taking:

- cimetidine, to treat stomach ulcers
- the antibiotic erythromycin, to treat bacterial infections
- Medicines to treat fungal infections, including itraconazole and Ketoconazole
- medicines to treat HIV, such as ritonavir (protease inhibitors), efavirenz and nevirapine
- tacrolimus, used after kidney or liver transplants
- Any other medicines to lower blood pressure
- barbiturates, to treat anxiety, sleeping problems and epilepsy
- phenytoin or carbamazepine, to treat seizures or epilepsy. If you are already taking any of these medicines, your doctor may prescribe higher than normal doses of Cardioplén for you to take
- Medicines containing St John's wort (*Hypericum perforatum*) (herbal product used to treat depression) may reduce the effect of Cardioplén and should therefore be avoided.

Cardioplén with food and drink

Do not drink grapefruit juice at the same time or soon after taking Cardioplén because grapefruit juice can increase the blood levels of felodipine and affect the way it works. It is best to take your tablets on an empty stomach or after a light meal.

Pregnancy, breast-feeding and fertility

Pregnancy

Do not use Cardioplén if you are pregnant.

Breast-feeding

Tell your doctor if you are breast-feeding or about to start breast-feeding. Cardioplén is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed.

Driving and using machines:

Cardioplén can have minor or moderate influence on your ability to drive and use machines. If you experience headache, nausea, dizziness or fatigue your ability to react may be impaired. Caution is recommended especially at the start of treatment.

Cardioplén contains Lactose Monohydrate

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 Cardioplén

Always take Cardioplén exactly as your doctor has told you to. You should check with your doctor or pharmacist if you are not sure.

The label on the carton will tell you how many tablets you should take and when. It is very important that you take your tablets regularly. **Do not stop** treatment even if you feel better unless told to do so by your doctor.

Cardioplén is formulated so that you only have to take your tablets **once a day**. It is important that you take your tablets **at the same time each day**, preferably in the morning on an empty stomach or after a light meal not high in fat or carbohydrates. Your tablets must be swallowed whole with a glass of water and **not** with grapefruit juice. **Do not break, crush or chew your tablets.**

Please read the back of this leaflet →

High blood pressure

Adults and the elderly: the usual dose is 5 mg **once** a day. Your doctor may decide to increase your dose to a maximum of 20 mg of Cardioplen once a day or prescribe another medicine to treat your high blood pressure for you to also take whilst you are taking Cardioplen. The usual dose when treating this disease for a long time is 5-10 mg once a day.

Angina

Adults: the usual dose is 5 mg **once** a day. Your doctor may decide to increase your dose to a maximum of 10 mg of Cardioplen once a day.

Do **not** stop taking your medicine until your doctor tells you.

Children must **not** take this medicine.

If you have liver problems

The level of felodipine in your blood may be increased. Your doctor may lower the dose.

Elderly people

If you are elderly, your doctor may prescribe a lower starting dose of 2.5 mg for you to take once a day.

If you take more Cardioplen than you should

If you accidentally take more Cardioplen than you should, you may suffer from very low blood pressure and sometimes palpitations, high or, rarely, slow heart rate. Therefore, it is very important that you take the number of doses prescribed by your doctor. If you experience symptoms such as feeling faint, light-headedness or dizziness, contact your nearest casualty department or tell your doctor or pharmacist immediately. Remember to take the pack and any remaining tablets with you.

If you forget to take Cardioplen

Do not worry. Simply leave out that dose completely and then take your next dose at the right time. Do not take a double dose to make up for a missed dose.

If you stop taking Cardioplen

If you stop taking this medicine your condition may return. Please consult your doctor and seek advice before you stop taking Cardioplen. Your doctor will advise you how long to take your medicine.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Cardioplen can cause side effects, although not everyone gets them.

Allergic reactions, although serious, have been reported in isolated cases. If you experience any of the following, stop taking Cardioplen and contact your doctor or casualty department immediately:

- raised lumps on your skin (weal) or swelling of the face, lips, mouth, tongue and throat
- Mild enlargement of the gums has been reported in patients with an inflammation in the mouth (gingivitis/periodontitis). The enlargement can be avoided or reversed by careful oral hygiene.

If you experience **chest pains** when you first start taking Cardioplen, contact your doctor immediately.

Other side effects

The following side effects do not usually last long and are most likely to occur when you first start to take your medicine or if your dose has been increased. If they continue or if you are worried, contact your doctor or pharmacist immediately.

Very common: may affect more than 1 in 10 people

- Ankle swelling
- Common: may affect up to 1 in 10 people
- Headache
- Flushing

Uncommon: may affect up to 1 in 100 people

- Abnormally rapid heart rate
- Palpitations
- Too low blood pressure (hypotension)
- Nausea
- Abdominal pain
- Burning/prickling/numbness
- Rash or itching
- Fatigue
- Dizziness

Rare: may affect up to 1 in 1,000 people

- Fainting
- Vomiting
- Nettle rash
- Pain in joints
- Muscular pain
- Impotence/sexual dysfunction

Very rare: may affect up to 1 in 10,000 people

- Gingivitis (swollen gums)
- Increased liver enzymes
- Skin reactions due to increased sensitivity to sunlight
- Inflammation of small blood vessels of the skin
- A need to pass water frequently.
- Hypersensitivity reactions such as fever or swelling of the lips and tongue

If any of the side effects get 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 YellowCard Scheme at 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 Cardioplen

- Keep this medicine out of the sight and reach of children.
- Do not store above 25°C. Store in the original packaging.
- Do not use Cardioplen after the expiry date which is stated on the blister and carton. The expiry date refers to the last day of that 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 protect the environment.

6. Contents of the pack and other information

What Cardioplen contains:

- The active substance in your tablets is felodipine. Each tablet contains 2.5 mg, 5 mg or 10 mg of felodipine.
- The other ingredients are lactose monohydrate, cellulose microcrystalline, talc, hypromellose, povidone, propyl gallate, silica colloidal anhydrous, magnesium stearate, ferric oxide yellow (E172), ferric oxide red (E172), titanium dioxide (E171) and propylene glycol.

What Cardioplen looks like and the contents of the pack:

Cardioplen XL Tablets are round and biconvex in shape and are available in blister packs of 28 tablets. Each strength can be identified by its colour and marking.

2.5 mg tablets are yellow and marked with "2.5"

5 mg tablets are light pink and marked with "5"

10 mg tablets are reddish brown and marked with "10"

Marketing Authorisation Holder and Manufacturer:

The Marketing Authorisation holder and manufacturer is Chiesi Limited, 333 Styal Road, Manchester, M22 5LG, UK.

Is this leaflet hard to see or read? Phone 0161 488 5555 for help.

This leaflet was last approved in 03/2017