Cardioplen® 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 leafet. See section 4. What is in this leaflet:

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

Cardioplen 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). Cardioplen 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 Cardioplen

Do not take Cardioplen:

if you are allergic to felodipine, other calcium-channel blockers (e.g.

- amlodipine, nisoldipine or nifedipine) or any of the other ingredients in Cardioplen (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 Cardioplen 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 Cardioplen**

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 Cardioplen. 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

Any other medicines to lower blood pressure

than normal doses of Cardioplen for you to take

- and nevirapine tacrolimus, used after kidney or liver transplants
- 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

 Medicines containing St John's wort (Hypericum perforatum) (herbal product used to treat depression) may reduce the effect of Cardioplen

Cardioplen with food and drink **Do not drink grapefruit juice** at the same time or soon after taking Cardioplen 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.

Breast-feeding

breast-feed.

and should therefore be avoided.

Pregnancy, breast-feeding and fertility **Pregnancy** Do not use Cardioplen if you are pregnant.

Tell your doctor if you are breast-feeding or about to start breast-feeding. Cardioplen is not recommended for mothers who are breast-feeding,

Cardioplen contains Lactose Monohydrate

Driving and using machines: Cardioplen 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.

and your doctor may choose another treatment for you if you wish to

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 Cardioplen Always take Cardioplen 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.

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.

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

Cardioplen 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

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.

mg for you to take once a day.

missed dose.

Elderly people

If you take more Cardioplen than you should If you accidentally take more Cardioplen than you should, you may suffer

If you are elderly, your doctor may prescribe a lower starting dose of 2.5

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

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

Please read the back of this leaflet →

feeling faint, light-headedness or dizziness, contact your nearest casualty department or tell your doctor or pharmacist immediately. Remember to

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

Common: may affect up to 1 in 10 people

Ankle swelling

Flushing

Uncommon: may affect up to 1 in 100 people

Headache

 Palpitations • Too low blood pressure (hypotension)

• Abnormally rapid heart rate

- Nausea
- Abdominal pain Burning/prickling/numbness
- Rash or itching Fatigue
- Dizziness

Vomiting

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

Nettle rash

Fainting

- · Pain in joints
- Muscular pain
- Impotence/sexual dysfunction

pharmacist.

- 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

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/

effects not listed in this leaflet, please tell your doctor or

yellowcard. By reporting side effects you can help provide more information

Reporting of side effects

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.

What Cardioplen contains:

marking.

- 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
- 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),

What Cardioplen looks like and the contents of the pack: Cardioplen XL Tablets are round and biconvex in shape and are available in

titanium dioxide (E171) and propylene glycol.

2.5 mg tablets are yellow and marked with "2.5" 5 mg tablets are light pink and marked with "5"

Styal Road, Manchester, M22 5LG, UK.

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

blister packs of 28 tablets. Each strength can be identified by its colour and

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