

CORDIPIN RETARD TABLET

Nifedipine 20 mg

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What Cordipin retard is used for

The drug is intended for treatment of all kinds of high blood pressure and all kinds of angina pectoris (chest pain), particularly vasospastic and chronic stable one.

How Cordipin retard works

Nifedipine inhibits the influx of calcium into the cells of the heart muscle and the muscle cells in the walls of arteries. It decreases the consumption of oxygen directly by reducing heart work. The oxygen demand is also indirectly decreased as the heart is relieved. Cordipin retard tablet is a prolong-release tablet. The release of nifedipine is slower so nifedipine achieves the maximum concentrations in 2 to 4 hours and its effect persists for 10 to 12 hours.

Before you use Cordipin retard

When you must not use it

- if you are allergic (hypersensitive) to nifedipine or any of the other ingredients of Cordipin retard;
- if you have ever had an allergic reaction to similar drugs (dihydropyridines);

- if you have impaired aortic valve (aortic stenosis);
 - if you have a disorder of porphyrin metabolism (a type of metabolic disorder called porphyria);
 - if you are pregnant or are breast-feeding.
- Patients with insufficient blood perfusion of organs, poor oxygen supply and too low blood pressure (cardiogenic shock) must not take the medicine.

Before you start to use it

Contact your doctor immediately:

- if you feel pain or tightness in your chest after the first dose of Cordipin retard;
- if during treatment with Cordipin retard you suddenly experience more frequent, stronger and longer attacks of chest pain both at rest and during physical activity;
- if during treatment with Cordipin retard you notice swelling of the ankles and shortness of breath during physical activity;

Measure your blood pressure and pulse regularly during treatment with Cordipin retard. Ask your doctor about the appropriate blood pressure and pulse values and the frequency of medical examinations.

At the beginning of treatment, more frequent checkups are required, especially

- if you have diabetes,
- if you have impaired liver function,
- if you have very high or low blood pressure,
- if you have increased pulmonary artery pressure,
- if you have severe heart failure,
- if you are a patient with hypertrophic cardiomyopathy (thickened heart wall and reduced left ventricular chamber size),
- if you are an elderly patient,
- if you have unstable angina pectoris (a type of chest pain).

Do not give Cordipin retard to children because its efficacy and safety in children have not been sufficiently investigated.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Be sure to tell your doctor if you are taking medicines used to treat:

- high blood pressure,
- angina pectoris (chest pain),
- heart failure,
- heart rhythm disorders(quinidine),
- gastrointestinal ulcers (cimetidine),
- tuberculosis (rifampicin), chronic bronchitis or asthma (theophylline),
- fungal (itraconazole), viral (cyclosporine, indinavir, ritonavir, saquinavir)
- epilepsy (carbamazepine, phenytoin).

Also tell your doctor if you are taking medicines for immune system suppression (tacrolimus). Concomitant administration of nifedipine and magnesium sulphate is not recommended because it is dangerous and may threaten your health.

Concomitant administration of Cordipin retard and some of the medicines used for the above diseases may change the effect of these medicines or the effect of Cordipin retard.

If your doctor refers you to a methacholine bronchial provocation test, tell him/her that you are taking Cordipin retard. Prior to scheduled surgery, be sure to tell your doctor that you are taking Cordipin retard.

How to use Cordipin retard

How much to use

The usual starting and maintenance dose of Cordipin retard is 1 tablet twice daily. If necessary, the doctor may

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increase the dosage to 2 tablets twice daily. In patients with Prinzmetal's (vasospastic) angina, the daily dose may be increased to 80 mg or maximum 120 mg daily.

When to use it

Cordipin retard should be taken twice daily. Take the tablet whole with a glass of water. You must not break, crush or chew it.

How long to take it

Cordipin retard tablet is intended to be used in long term treatment. You can only stop taking this medicine if you are advised to do so by your doctor.

If you have the impression that the effect of Cordipin retard is too strong or too weak, talk to your doctor or pharmacist.

If you forget to use it

Do not take a double dose to make up for a forgotten dose. Try to get into the habit of taking the medicine regularly and at the same time each day. Continue taking your tablets as prescribed.

If you use too much (overdose)

Overdosage could result in excessive peripheral vasodilation with subsequent marked and probably prolonged hypotension. Hypotension is usually manifested as nausea, accelerated heartbeat, dizziness, lightheadedness or fainting. If this occurs, you should lie down, elevate the legs with a pillow and call the doctor. If large quantities of prolonged-release tablets have been ingested, the signs of intoxication can appear only after a few hours (3 or 4 hours). The signs of intoxication are lowered blood pressure, shock, slow heartbeat or accelerated heartbeat, heart failure and convulsions. After the ingestion of a large number of tablets, the doctor should be consulted as soon as possible so that he may determine the appropriate treatment (gastric

lavage, adsorption to activated charcoal and symptomatic treatment).

While you are using it

Things you must do

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

Things you must not do

During treatment with Cordipin retard, do not drink grapefruit juice because they increase the side effect of the medicine on blood pressure and lead to more frequent side effects.

Do not give the medicine to children.

Things to be careful of

Do not drive or use machines until you know how you react to treatment. The medicine can cause dizziness in individual patients, especially at the start of treatment or following the consumption of alcohol, and thus indirectly and transiently reduce the ability to drive and use machines.

Side effects

Side effects are transient and mild and usually do not necessitate discontinuation of treatment. The most common side effects are dizziness, lightheadedness, headache, fatigue, weakness, facial flushing, heat sensation; swelling, particularly of the ankles and legs which usually responds to diuretic therapy. Nifedipine can alter certain laboratory values and tests (mainly liver ones). These changes are not necessarily associated with clinical signs (although cases of yellowing of the whites of the eyes or skin – cholestasis and jaundice – have been reported).

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 Cordipin retard

Storage

Keep out of the reach and sight of children. Do not store over 25°C. Protect from light and moisture. Do not use your medicine after the expiry date which is stated on the pack after 'EXP'. The expiry date refers to the last day of that month.

Disposal

No special requirements. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

What it looks like?

The prolonged-release tablets are yellow, round, bevel-edged, film-coated and slightly biconvex tablets.

Ingredients

Each prolonged release tablet contains 20 mg nifedipine.

Excipients: microcrystalline cellulose, glyceryl palmitostearate, talc, anhydrous colloidal silica, sodium laurilsulfate, magnesium stearate and povidone in the tablet core, and methacrylic acid

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copolymer, talc, titanium dioxide (E171), macrogol 4000 and quinoline yellow colour (E104) in the coating.

MAL NO:

MAL19900657A

Manufacturer

KRKA, d.d., Novo mesto,
Šmarješka cesta 6, 8501 Novo mesto, Slovenia

Product Registration Holder

PAHANG PHARMACY SDN.
BHD., Lot 5979, Jalan Teratai, 5
½ Miles, Off Jalan Meru, 41050
Klang, Selangor, Malaysia

Date of revision

30/12/2013