

CORDIPIN TABLET

Nifedipine 10 mg

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What Cordipin is used for

Nifedipine is indicated for the management of increased blood pressure (hypertension) and chest pain associated to heart disease (vasospastic angina pectoris and of chronic stable angina pectoris).

How Cordipin works

Cordipin works by relaxing and expanding the blood vessels. This makes the blood flow more easily and lowers blood pressure. Lower blood pressure reduces the strain on your heart. Cordipin also works by relaxing and expanding the arteries supplying the heart. This allows more blood and oxygen to reach the heart and decreases the strain on it. Your chest pain (angina) attacks will be less severe and less frequent if there is less strain on the heart

Before you use Cordipin

When you must not use it

- if you are hypersensitive to nifedipine or any other ingredient of the drug,
- if you have cardiogenic shock (a heart problem, during which you may become breathless, pale and have a cold sweat and dry mouth),

- if you have advanced aortic stenosis (a narrowing of the aortic heart valve),
- if you have porphyria (a type of metabolic disorder),
- if you are pregnant or are breast-feeding.

Before you start to use it

If you suffer from severe heart diseases (hypertrophic cardiomyopathy, unstable angina pectoris), diabetes, have severe liver problem or severely increased blood pressure in lung vessels (pulmonary hypertension) and you are an elderly person, you will be closely monitored by your doctor during the introduction of nifedipine therapy.

If you have severe heart disease, more frequent chest pain attacks (angina pectoris) may occur at the beginning of treatment.

If you have different type of chest pain, called unstable angina pectoris, or those having recovered from heart attack should not take immediate-release nifedipine. In this case, the doctor should be consulted.

Mild to moderate swelling of ankles and legs, typically associated with dilatation of the arteries and not due to heart problems, occurs in about one in ten patients treated with nifedipine. This swelling occurs primarily in the lower extremities and usually responds to therapy with diuretics.

Due to a lack of experience in children, nifedipine should not be used in this age group.

Taking other medicines

You should inform your doctor if you take any other drug. Tell your doctor if you are taking:

- blood pressure lowering drugs (beta blockers, drugs for increasing urine excretion) and certain drugs for treating heart diseases (nitroglycerin and prolonged-release isosorbide),

- drugs for treatment of chronic pain (fentanyl),
- magnesium infusion,
- drugs for treating heart conditions (digoxin, quinidine),
- drugs for treating epilepsy (phenytoin, carbamazepine),
- drugs usually given to patients after organ transplantation (tacrolimus, cyclosporine),
- drugs for treating asthma (theophylline),
- drugs for treating bacterial infections (rifampicin),
- drugs for treating stomach ulcers (cimetidine),
- drugs for treating fungal infections (itraconazole, fluconazole, ketoconazole),
- drugs for treating HIV virus infection (ritonavir, saquinavir).

During treatment with nifedipine it is not recommended to drink great amounts of grapefruit juice because it can elevate levels of nifedipine in the blood, thus increasing its effect.

How to use Cordipin

How much to use

The starting dose is one tablet (swallowed whole) 3 times/day. The usual effective dosage range is 10-20 mg three times a day. Doses above 120 mg daily are rarely necessary. More than 180 mg per day is not recommended.

When to use it

Cordipin tablets are to be taken after meals. They should be swallowed whole with a glass of water and must not be broken or chewed.

How long to use it

You should take Cordipin for as long as your doctor told you.

If you forget to use it

Do not take a double dose to make up for a forgotten dose.

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Try to get into the habit of taking the medicine regularly and at the same time every day. If you miss a dose, take it as soon as possible. However, if it is only a few hours before the next dose is due, take only the next scheduled dose and leave out the forgotten one.

If you take too much (overdose)

Overdosage could result in excessive peripheral vasodilation with subsequent marked hypotension. Hypotension is usually manifested as nausea, accelerated heartbeat, dizziness, lightheadedness or fainting. In such a case, you should lie down, elevate the legs with a pillow and call the doctor.

If large quantities of tablets are ingested, 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 can determine the appropriate treatment (gastric lavage, adsorption to activated charcoal and symptomatic treatment).

While you are using it

Especially at the beginning of treatment and if certain drugs intended for treatment of high blood pressure (beta blockers) are taken concomitantly, blood pressure may fall substantially, which some patients tolerate poorly. In patients taking beta blockers, heart failure may occur after the introduction of nifedipine therapy. The doctor will make more frequent appointments for control examinations, which you should pass regularly even if you feel well.

Things you must do

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

Things you must not do

Do not drive or use machines until you find out how you respond to treatment.

Particularly at the beginning of treatment, the medicine can cause dizziness in individual patients and thus indirectly and transiently reduce the ability to drive and use machines.

During treatment with Cordipin, do not drink grapefruit juice or alcoholic drinks. Alcohol and grapefruit juice increase the effect of the medicine on blood pressure and the frequency of side effects.

Things to be careful of

Cordipin contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, talk to your doctor before taking this medicine.

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 (around the ankles, feet, shanks or around the eyes), faster heart beat, nausea and heartburn. Rarely, transient reduction of blood pressure may occur. Less frequently, rapid and irregular heart beats, nasal and chest congestion, shortness of breath, diarrhea, constipation, flatulence, joint stiffness, muscle cramps, shakiness, nervousness, jitteriness, sleep disturbances, blurred vision, difficulties in balance, dermatitis, itching, urticaria, fever, sweating, chills, sexual difficulties may occur. Fainting, reduction in blood platelets, which increases risk of bleeding or bruising, anemia, reduction in blood white cells, skin rash, allergic liver inflammation, swelling of the gums, depression, paranoid syndrome, transient blindness at

the peak of plasma level, a disorder characterized by burning pain, warmth and redness of the extremities called erythromelalgia and a type of inflammation of the joints may also occur.

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 have been reported).

The patient should inform his doctor about any undesirable effects, even about those which are not mentioned in the insert leaflet.

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

Storage

Keep out of reach and sight of children.
Do not store above 25°C and 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.

CORDIPIN TABLET

Nifedipine 10 mg

Product Description

What it looks like

The product appears as round, yellow, slightly biconvex, bevel-edged, film-coated tablets, score on one side.

Ingredients

Each tablet contains 10 mg nifedipine.

Inactive ingredients

Maize starch, lactose monohydrate, povidone, sodium lauryl sulfate, talc, pregelatinized starch, anhydrous colloidal silica in the tablet core and methacrylate copolymer, talc, titanium dioxide (E171), polyethylene glycol and yellow colour (E104) in the coating layer of the tablet.

MAL NO:

MAL19861588A

Manufacturer

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

Product Registration Holder

PAHANG PHARMACY SDN.
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Date of revision

8/11/2013