

NIFEDIPRESS[®] MR 10 Modified-release tablets

NIFEDIPRESS[®] MR 20 Modified-release tablets

(Nifedipine)

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 your 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

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1. What Nifedipress MR Tablets are and what they are used for

Nifedipress MR 10 & 20 Modified-release tablets (referred to as 'Nifedipress MR' throughout this leaflet) are modified-release tablets containing the active substance nifedipine 10 mg and 20 mg respectively.

Nifedipine MR Tablets contains nifedipine, which belongs to a group of medicines called calcium-channel blockers.

Nifedipress MR is used to treat high blood pressure (hypertension) and to prevent the condition called chronic stable angina pectoris (chest pain coming from the heart) in adults.

• For high blood pressure: Nifedipress MR 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.

• For angina: Nifedipress MR 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 angina attacks will be less severe and less frequent if there is less strain on the heart.

2. What you need to know before you take Nifedipress MR Tablets

Do not take Nifedipress MR

- if you are allergic to the active ingredient (nifedipine), to any other similar medicines known as *dihydropyridines* (e.g. amlodipine, felodipine, isradipine, nisoldipine or nimodipine) or to any of the other ingredients of this medicine (listed in section 6).
- if you are pregnant, or likely to become pregnant
- if you have narrowing (*stenosis*) of the aortic heart valve (one of the valves of the heart)
- if you have unstable angina (heart pain)
- if you have suffered a heart attack within the last month
- if you have collapse of the circulation (cardiogenic shock)
- if you get a sudden angina attack. Nifedipress MR will not help relieve symptoms of angina quickly
- if you have taken nifedipine before and found your heart pain got worse
- if you have very high blood pressure (malignant hypertension)
- if you have Porphyria
- if you have a "Knock pouch" (a surgically constructed intestinal reservoir with an opening through the abdominal wall) in your gut.
- if you are taking rifampicin, an antibiotic (for tuberculosis treatment for example)

Tell your doctor and do not take Nifedipress MR if any of these apply to you. If you are unsure whether you might have any of these conditions, please ask your doctor.

Warnings and precautions

Talk to your doctor or pharmacist before taking Nifedipress MR

- if you have low blood pressure (may cause dizziness or fainting on standing up). Your blood pressure may be decreased further by this treatment
- if you have heart problems other than chronic stable angina (heart failure)
- if you have diabetes. The treatment for your diabetes may need to be adjusted
- if you are on kidney dialysis. If you have a very high blood pressure and a low blood volume, you might experience a sudden drop in your blood pressure when you take Nifedipress MR
- if you are breastfeeding. If you need to take Nifedipress MR, you should stop breastfeeding before you start to take this medicine.
- if your liver is not working properly. Your doctor may need to do some blood tests.

You may also be given a lower dose of the medicine

Tell your doctor:

- If your chest pain (angina) gets worse (comes on more often or more severely) over a matter of hours or days. You may be advised not to take Nifedipress MR.
- If you have chest pains after taking your first dose of Nifedipress MR. Your doctor may wish to change your treatment.
- If you notice increased breathlessness.
- If you notice swelling of the ankles.

Tell your doctor before you take the next dose if any of these apply to you.

Also tell your doctor:

- If you are giving a urine sample. Nifedipress MR may interfere with the results of certain urine tests.

Children and adolescents

Nifedipress MR is not recommended for use in children and adolescence below 18 years of age, because there are only limited data on the safety and efficacy in this population.

Other medicines and Nifedipress MR

Tell your doctor if you are taking, have recently taken or might take any other medicines.

Some medicines may affect the way Nifedipress MR works. **Tell your doctor** if you are taking **any of the following medicines:**

- **Other medicines to treat high blood pressure.**
- **Rifampicin** (an antibiotic).
- **Cimetidine** (to treat stomach ulcers).
- **Digoxin, diltiazem, quinidine or beta-blockers** (to treat heart conditions).
- **Quinupristin/dalfopristin** (a combination antibiotic).
- **Phenytoin, carbamazepine or valproic acid** (to treat epilepsy).
- **Cisapride** (to treat reduced movements of the gullet and stomach).
- **Magnesium sulfate injections during pregnancy** (may cause a severe fall in blood pressure).
- **Erythromycin** (an antibiotic).
- **Ketoconazole, itraconazole or fluconazole** (anti-fungal medicines).
- **Indinavir, nelfinavir, ritonavir, saquinavir or zalcitabine** (to treat HIV).
- **Fluoxetine or nefazodone** (to treat depression).
- **Tacrolimus** (to prevent the rejection of transplanted organs).
- **Phenobarbital** (usually to treat insomnia or anxiety).
- **St John's Wort** (herbal medicine).

If you are unsure about your other medication, please talk to your doctor or pharmacist before taking Nifedipress MR. They may need to alter your treatment or give you some special advice.

Nifedipress MR with food, drink and alcohol

Nifedipress MR may be taken with or without food. As a safety precaution, do not take with alcohol.

Do not drink grapefruit juice or eat grapefruit while taking Nifedipress MR.

Do not start taking Nifedipress MR within 3 days of drinking grapefruit juice or eating grapefruit. Tell your doctor if you have had grapefruit or grapefruit juice in this time. Also, do not drink grapefruit juice or eat grapefruit whilst taking Nifedipress MR. Grapefruit juice is known to increase the blood levels of the active ingredient, nifedipine. This effect can last for at least 3 days.

Pregnancy, breast-feeding and fertility

Do not take Nifedipress MR if you are pregnant or breastfeeding.

Medicines like Nifedipress MR have been shown in laboratory experiments to impair sperm function. If you are male and have been unsuccessful in fathering a child please consult your doctor.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Driving and using machines

Nifedipress MR may make you feel dizzy, faint, extremely tired or have visual disturbances. Do not drive or operate machinery if you are affected in this way.

This may become more likely when you first start treatment, if you change medication or if you have drunk alcohol.

Nifedipress MR contains lactose.

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 Nifedipress MR Tablets

Always take your medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

- **The recommended dose** is one 10 mg or one 20 mg tablets every 12 hours (i.e. twice per day). Your doctor may increase

or decrease the dose depending on how well your blood pressure or angina is being controlled. Doses of up to 80 mg per day (40 mg every 12 hours) may be prescribed by your doctor if considered necessary.

- Lower doses of this medicine may be prescribed by your doctor for older people.
- **If you have problems with your liver** your doctor will monitor you carefully. A reduction in your nifedipine dose may be required.
- **Swallow the tablets whole with a little water. The tablets should not be crushed, chewed, divided or dissolved.** You can take Nifedipress MR either with or without food. Do not take them with grapefruit juice.

• Duration of treatment

Treatment for high blood pressure or angina is usually for life. Your doctor will monitor your treatment and check your blood pressure. **Continue to take the tablets** for as long as your doctor has told you to.

DO NOT EXCEED THE STATED DOSE.

Use in children and adolescents

Nifedipress MR is not recommended for use in children and adolescents below 18 years of age, because there are only limited data on the safety and efficacy in this population.

If you take more Nifedipress MR tablets than you should

If you take more tablets than you should **go straight to your casualty department**. Take any remaining tablets, box and this leaflet with you so the medical staff know exactly what you have taken.

Taking too many tablets may cause your blood pressure to become too low causing dizziness particularly on standing and your heartbeats may speed up or slow down. It may also lead to an increase in your blood sugar level or an increase in the acidity of your blood, swelling in the lungs, low blood oxygen levels and disturbances in consciousness, possibly leading to unconsciousness.

If you forget to take Nifedipress MR

Do not worry. Take the missed dose as soon as you remember, waiting 12 hours before taking your next dose.

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

If you have any further questions about this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

It is important that you are aware of what these side effects may be. They are usually mild and disappear after a short time.

Stop taking Nifedipress MR and seek urgent help immediately if you suffer from:

- An increase in chest pain at the start of treatment
- An allergic reaction and experience difficulty breathing, with or without swelling of the face, lips, tongue, and/or throat which may cause difficulty in swallowing.

Also stop taking Nifedipress MR and talk to your doctor immediately if you:

- Start shaking or experience a loss of eyesight caused by a sudden drop in blood pressure
- Notice a fast heart beat (*tachycardia*)
- Notice a shortness of breath or difficulty breathing (*dyspnoea*)
- Notice a yellowing of the skin and eyes caused by liver problems such as allergic hepatitis, intra-hepatic cholestasis
- Notice flaking or purple blotching of the skin caused by exfoliative dermatitis, erythema multiform or pemphigoid reactions
- Develop a skin reaction or blistering / peeling of the skin and/or mucosal reactions (in the mouth/nose or at the penis/vagina) (Toxic Epidermal Necrolysis)
- Notice itching (possibly severe), a rash or hives

Other side effects

Apart from the side effects listed above, these are the other side effects of Nifedipress MR, starting with the more common ones:

Common *may affect up to 1 in 10 people*

- headache
- general feeling of being unwell
- constipation
- swelling, particularly of the ankles and legs

Uncommon *may affect up to 1 in 100 people*

- stomach pain (abdominal pain)
- unspecified pain
- chills
- low blood pressure when standing up (symptoms include fainting, dizziness, light headedness, occasional palpitations, blurred vision and sometimes confusion)
- fainting
- irregular heartbeat (*palpitations*)
- dry mouth
- indigestion or upset stomach
- wind (*flatulence*)
- feeling sick (*nausea*)
- muscle cramps
- joint swelling
- sleep disorders
- anxiety or nervousness
- reddening of the skin
- nosebleeds
- nasal congestion
- sensation of spinning or whirling motion (*vertigo*)
- migraine
- dizziness

- trembling
- increase in the need to pass water (urinate)
- painful or difficult urination
- inability to achieve or maintain an erection (*impotence*)
- blurred vision
- temporary increase in certain liver enzymes (shown on blood test).

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

- pins and needles
- change in mood
- inflammation of the gums, tender or swollen gums, bleeding gums

Not known: *frequency cannot be estimated from the available data*

- a reduction in the number of white blood cells (leucopenia)
- a more severe decrease in a specific class of white blood cells (agranulocytosis)
- depression
- increased blood sugar (hyperglycaemia)
- decreased skin sensitivity (hypoesthesia)
- sleepiness
- lethargy
- insufficient blood flow to the brain
- eye pain
- chest pain (angina pectoris)
- decreased blood flow to your heart
- flushing
- vomiting
- heartburn or indigestion (gastroesophageal sphincter insufficiency)
- diarrhoea
- sensitivity to light (photosensitivity allergic reaction)
- small, raised areas of bleeding in the skin (palpable purpura)
- spider veins
- joint pain
- muscle pain
- muscle weakness
- fever
- worsening of myasthenia gravis
- development of breast tissue in older men on long term therapy has been reported

Because of the nature of coronary heart disease, heart attacks have occurred in patients treated with the active ingredient, nifedipine. It has not been shown that these heart attacks were due to treatment with nifedipine.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. 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 or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Nifedipress MR Tablets

Keep this medicine out of the sight and reach of children.

Do not store above 25°C.

Store your medicine in the original package in order to protect from strong light and only remove the tablet from the blister strip when you are about to take it.

Do not use this medicine after the expiry date which is stated on the outer carton and on each blister strip after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Nifedipress MR contains

The active substance is nifedipine. **Nifedipress MR 10 & 20** are modified-release tablets. Each tablet contains either 10 mg or 20 mg nifedipine respectively.

The other ingredients are: colloidal anhydrous silica, microcrystalline cellulose, lactose monohydrate, polysorbate 80, starch pregelatinized, magnesium stearate, hypromellose 2910, macrogol 6000, titanium dioxide E-171, purified talc, iron oxide red E-172, purified water and carnauba wax.

What Nifedipress MR Tablets look like and contents of the pack

Nifedipress MR 10 and 20 tablets are modified-release, brownish pink, round, film-coated tablets which come in two different tablet sizes. Nifedipress MR 10 is the smaller tablet of the two.

Nifedipress MR 10 and Nifedipress MR 20 are available in packs of: 28 tablets in foil blister strips; 30 tablets in foil blister strips; 56 tablets in foil blister strips. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Dexcel® - Pharma Ltd., 7 Sopwith Way, Drayton Fields, Daventry, Northamptonshire, NN11 8PB, UK

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