

NIFEDIPINE CAPSULES 5mg and 10mg

[Nifedipine]

PACKAGE LEAFLET: INFORMATION FOR THE USER

The product names - Nifedipine Capsules 5mg and Nifedipine Capsules 10mg are collectively referred to as Nifedipine Capsules in this leaflet.

Read all of this leaflet carefully before taking this medicine because it contains important information for you.

- Keep this leaflet. You may have to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Nifedipine Capsules are and what they are used for
2. What you need to know before you take Nifedipine Capsules
3. How to take Nifedipine Capsules
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1. What Nifedipine Capsules are and what they are used for

The active ingredient nifedipine, is one of a group of medicines called calcium antagonists. These relax and expand blood vessels.

Nifedipine Capsules are used for:

- High blood pressure
- To reduce the frequency of angina attacks
- Raynaud's phenomenon, a condition in which the circulation of blood to fingers and toes is reduced.

2. What you need to know before you take Nifedipine Capsules**Do not take Nifedipine Capsules:**

- If you are allergic to nifedipine or any of the other ingredients of this medicine (listed in section 6)
- If you have previously had an allergic reaction to the active ingredient nifedipine or to any other similar drugs (known as dihydropyridines). If you are unsure about this, ask your doctor
- If you are taking the antibiotic, rifampicin
- If you have been told that you have a narrowing (stenosis) of the aortic valve of the heart or have experienced a collapse which was caused by a heart problem
- For the treatment of a heart attack or within one month of a heart attack
- To treat an angina attack
- If you have collapse of the circulation (cardiogenic shock)
- If your blood pressure is continuing to rise despite treatment. This is a condition known as malignant hypertension.
- If you have Porphyria
- If you have a "Kock pouch" (a surgically constructed intestinal reservoir with an opening through the abdominal wall) in your gut.

If the severity or frequency of your angina has rapidly worsened over a matter of hours or days, you must contact a doctor. You may be advised not to take Nifedipine Capsules.

If you are unsure whether you might have any of these conditions, please ask your doctor.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Nifedipine Capsules:

- If you experience chest pains within 30-60 minutes of taking your FIRST dose of nifedipine, contact your doctor BEFORE YOU TAKE THE NEXT DOSE as he or she may change your treatment
- If you are taking other medicines that affect the way your liver metabolises nifedipine (see section: Other medicines and Nifedipine Capsules)
- If you have impaired liver function
- If you are pregnant
- If you are breast-feeding
- If you are pregnant and have to have intravenous magnesium sulphate as there may be a sudden fall in blood pressure.

Please tell your doctor if you:

- Suffer from low blood pressure and have nifedipine prescribed for angina or Raynaud's syndrome
- Heart condition where your heart cannot cope with increased strain (poor cardiac reserve), or your heart condition gets worse
- Have increased breathlessness or swelling of the ankles
- Are a diabetic as your treatment may need to be adjusted

- Are having dialysis and have a very high blood pressure as you may experience a sudden drop in blood pressure.

Your doctor may want to monitor your blood pressure during treatment with Nifedipine Capsules.

Also tell your doctor:

- If you are giving a urine sample as nifedipine may interfere with the results of certain urine tests
- If you are a man who has been unable to father a child by IVF. Drugs like nifedipine have been shown to impair sperm function.

Other medicines and Nifedipine Capsules

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. In particular, tell your doctor or pharmacist if you are taking:

- Other drugs to treat high blood pressure
- Cimetidine, to treat stomach ulcers
- The medicines digoxin, diltiazem, quinidine or beta-blockers, which are used to treat heart conditions
- The antibiotics rifampicin and combination treatment quinupristin/dalfopristin
- The anti-epileptic drugs phenytoin, carbamazepine or valproic acid
- Cisapride, a drug used to treat reduced movements of the gullet and stomach.

The effect of the following drugs on nifedipine is uncertain. Therefore, as an additional precaution, please tell your doctor or pharmacist if you are taking:

- The antibiotic erythromycin
- The antifungals ketoconazole, itraconazole or fluconazole
- The HIV protease inhibitors indinavir, nelfinavir, ritonavir, saquinavir or amprenavir
- The antidepressant drugs fluoxetine and nefazodone
- Tacrolimus, an immunosuppressant used to prevent the rejection of transplant organs
- The barbiturate phenobarbital, used primarily to treat insomnia and anxiety
- Magnesium sulphate injections during pregnancy (may cause a severe fall in blood pressure).
- St John's Wort (herbal medicine).

Nifedipine Capsules with food, drink and alcohol

Nifedipine Capsules may be taken with or without food. As a safety precaution, do not take with alcohol. You should not start taking Nifedipine Capsules within three days of drinking grapefruit juice. If you have, speak to your doctor. In addition you should not drink grapefruit juice whilst taking Nifedipine Capsules. This is because grapefruit juice is known to increase the blood levels of the active ingredient, nifedipine. This effect lasts for at least three days after the last ingestion of grapefruit juice.

Pregnancy, breast-feeding and fertility

Do not take this medicine if you are pregnant or breast-feeding.

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

Driving and using machines

It is possible that you may react to nifedipine.

Reactions may be dizziness, lethargy and visual disturbances but can vary in intensity from individual to individual and may impair your ability to drive or operate machinery. This applies particularly at the start of treatment, on changing the medication and in combination with alcohol.

Nifedipine Capsules contain Sunset yellow (E110)

May cause allergic reactions.

3. How to take Nifedipine Capsules

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

The capsules should be swallowed with a little water. You should not take your capsule(s) with grapefruit juice.

- The recommended dose is 5mg every 8 hours. The dose may be increased to a maximum dose of 20mg every 8 hours.
- If you suffer from a liver disorder, your doctor may want to start your treatment on a low dose and increase it with careful monitoring of your blood pressure or angina.

Elderly: lower doses of this medicine may be prescribed by your doctor.

It is possible that you may have to take these capsules indefinitely. You may want to discuss this with your doctor.

Children

Nifedipine Capsules are 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.

DO NOT EXCEED THE PRESCRIBED DOSE.**If you take more Nifedipine Capsules than you should**

Exceeding the correct dosage or taking an overdose may cause your blood pressure to become too low and your heart beats to become irregular. Also, it may lead to dizziness, confusion, visual disturbances, low blood oxygen levels and possibly unconsciousness. If you take more than the prescribed dose, or in the event of an overdose, seek medical advice immediately and, if possible take your capsules or the box with you to show the doctor.

If you forget to take Nifedipine Capsules

You should take your normal dose immediately and then continue taking your capsules as prescribed, waiting 8 hours before taking your next dose. Do not take a double dose to make up for a forgotten dose.

If you stop taking Nifedipine Capsules

You should take Nifedipine Capsules for as long as your doctor tells you to. It may be dangerous to stop taking Nifedipine Capsules before talking to your doctor.

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

4. Possible side effects

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

Serious side effects of this medicine**If you notice:**

- Severe, sudden generalised allergic reaction including very rarely life-threatening shock (e.g. difficulty in breathing, drop of blood pressure, fast pulse) or swelling (including potentially life-threatening swelling of the airway)
- Other allergic reactions causing swelling under the skin (possibly severe and including swelling of the larynx that may result in a life-threatening outcome)
- Fast heart beat (tachycardia)
- Shortness of breath (frequency not known) or difficulty in breathing
- Mild to moderate allergic reactions
- Itching (possibly severe), a rash or hives.

Contact your doctor immediately and do not take the next dose as these may be the first signs of allergic reaction which may become severe.

If you 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).

Contact your doctor immediately before you continue treatment as these may be signs of a severe reaction.

Other side effects:**Common: may affect up to 1 in 10 people**

- Headache
- Swelling, particularly of the ankles and legs
- Constipation
- Generally feeling unwell.

Uncommon: may affect up to 1 in 100 people

- Anxiety or nervousness
- Sleep disorders
- Sensation of spinning or whirling motion (vertigo)
- Migraine
- Dizziness
- Trembling
- Visual disturbances
- Irregular heartbeat (palpitations)
- Low blood pressure (hypotension)
- Fainting (syncope)
- Nasal congestion
- Nose bleeds
- Stomach pain (gastrointestinal and abdominal pain)
- Feeling sick (nausea)
- Indigestion (dyspepsia)
- Wind (flatulence)
- Dry mouth
- Temporary increase in certain liver enzymes
- Reddening of the skin
- Muscle cramps
- Joint swelling
- Increase in the need to pass water (urinate)
- Painful or difficult urination
- Inability to achieve or maintain an erection (impotence)
- Unspecific pain
- Chills
- Blurred vision.

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

- Pins and needles (paraesthesia)
- An abnormal unpleasant sensation felt when touched (dysaesthesia)

- changes in mood
- inflammation of the gums, tender or swollen gums, bleeding gums (gingival hyperplasia).

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 cell (agranulocytosis)
- Depression
- Increased blood sugar (hyperglycaemia)
- Decreased skin sensitivity (hypoesthesia)
- Drowsiness (somnolence)
- Lethargy
- Insufficient blood flow to the brain
- Eye pain
- Decreased blood flow to your heart
- Flushing
- Chest pain (angina pectoris)
- Being sick (vomiting)
- Heartburn (gastroesophageal sphincter insufficiency)
- Diarrhoea
- Yellowing of the whites of the eyes or skin (jaundice)
- 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.

All of the symptoms above usually go away when treatment with nifedipine is stopped.

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 Yellow Card Scheme at: 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 Nifedipine Capsules

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

Do not use this medicine after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

Store in the original container.

Do not store above 25°C.

The capsules should be protected from strong light, so only remove the capsule from the container or blister strip when you are about to take it.

Do not use this medicine if you notice visible signs of deterioration.

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 Nifedipine Capsules contain**

The active substance(s) is nifedipine.

The capsules contain either 5mg or 10mg of nifedipine. The other ingredients are: Macrogols (Polyethylene glycol 400), Propylene glycol, Peppermint oil, Saccharin sodium.

Ingredients of the shell: Gelatin, Glycerol, Titanium dioxide (E171), Sunset yellow (E110), Andrisorb. Printing ink: Monogramming Ink S-1-18086 White (which contains Shellac Glaze (Modified)), Titanium dioxide, Isopropyl alcohol, N-Butyl alcohol and Propylene glycol).

What Nifedipine Capsules look like and contents of the pack**Nifedipine 5mg Capsules:**

Description: Orange oval, soft gelatine capsule with a clear liquid fill material printed G and NE 5.

Nifedipine 10mg Capsules:

Description: Orange oval, soft gelatine capsule with a clear liquid fill material printed G and NE 10.

Contents of pack: Blister pack

14 capsules in a blister, 6 blisters in a carton.

10 capsules in a blister, 9 blisters in a carton.

Marketing Authorisation Holder and Manufacturer:

Relonchem Limited, Cheshire House, Gorsey Lane, Widnes, Cheshire, WA8 0RP, UK.

Nifedipine Capsules 5mg: PL 20395/0311

Nifedipine Capsules 10mg: PL 20395/0286.

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