PACKAGE LEAFLET: INFORMATION FOR THE USER

NIFEDIPINE CAPSULES 5mg AND 10mg

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 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 possible 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**
4. **Possible side effects**
5. **How to store Nifedipine Capsules**
6. **Contents of the pack and other information**

1. WHAT NIFEDIPINE CAPSULES ARE AND WHAT THEY ARE USED FOR

Nifedipine Capsules contain nifedipine. This belongs to a group of medicines called calcium antagonists. Nifedipine works by relaxing and expanding blood vessels allowing blood to flow more easily.
Nifedipine is used in the treatment of high blood pressure and Raynaud's phenomenon (a condition where spasm of the blood vessels in the fingers causes them to go white, with numbness and discomfort). It is also used for the prevention of chronic stable angina pectoris.
Nifedipine Capsules should not be used for the treatment of acute attacks of angina.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE NIFEDIPINE CAPSULES

Do not take Nifedipine Capsules if:
- you are allergic to nifedipine, any other dihydropyridine drugs, or any of the ingredients in this medicine (listed in section 6) or other dihydropyridines such as amlodipine, felodipine, isradipine or nisolidipine.
- you have taken nifedipine before and found your heart pain got worse
- you have Porphyria
- you have collapse of the circulation (cardiogenic shock)
- you have aortic stenosis (narrowing of the opening of the aortic heart valve)
- you suffer with unstable angina
- you are having, or have had a heart attack in the last month
- you are taking rifampicin (see other medicines section)
- you get a sudden angina attack. Nifedipine capsules will not help relieve symptoms of angina quickly
- your blood pressure continues to rise despite treatment (malignant hypertension).
- you have a "Kock pouch" (a surgically constructed intestinal reservoir with an opening through the abdominal wall) in your gut.

This medicine is not recommended for use in children.

Warnings and precautions:
Talk to your doctor, pharmacist or nurse before taking this medicine:
- **If you have low blood pressure.** Your blood pressure may be decreased further by this treatment
- **If you have heart problems** other than chronic stable angina (heart failure)
- **If you are diabetic.** The treatment for your diabetes may need to be adjusted. If you have any questions about this, ask your doctor
- **If you are on kidney dialysis.** If you have very high blood pressure and a low blood volume, you might experience a sudden drop in blood pressure when you take Nifedipine Capsules
- **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 this medicine
- **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 Nifedipine Capsules
- **If you are taking other medications** (see other medicines section)
- **If you are giving a urine sample.** Nifedipine Capsules may interfere with the results of certain urine tests
- **If you are a man who has been unable to father a child** by *in vitro fertilisation*. Drugs like Nifedipine Capsules have been shown to impair sperm function
- **If you are, or might be pregnant**

Other medicines and Nifedipine Capsules:
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Some medicines may affect the way Nifedipine Capsules work. **Tell your doctor** if you are taking:
- **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, phenobarbital, carbamazepine** or **valproic acid** (to treat epilepsy)
- **Cisapride** (to treat reduced movements of the gullet and stomach)
- **Magnesium sulphate 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 **amprenavir** (to treat HIV)
- **Fluoxetine** or **nefazodone** (to treat depression)
- **Tacrolimus** (to prevent the rejection of transplanted organs).
- **Phenobarbital** (usually used 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 Nifedipine Capsules. They may need to alter your treatment or give you some special advice.

Nifedipine Capsules with food, drink and alcohol:
This medicine can be taken with or without food.

Alcohol can increase the effect of Nifedipine, this may be dangerous. Ask your doctor or pharmacist for advice if you wish to drink alcohol while taking this medicine.

Do not drink grapefruit juice or eat grapefruit while taking Nifedipine Capsules.
Do not start taking Nifedipine Capsules 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 Nifedipine Capsules. 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
If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. You may be able to use nifedipine but only after special consideration and agreement by your doctor. Medicines like Nifedipine capsules 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.

Nifedipine has been shown to pass into breast milk in small amounts. It is not known if nifedipine might impact your baby. If you are breastfeeding or about to start breastfeeding, talk to your doctor before taking nifedipine or if you have any concerns about your baby whilst taking this medicine.

Driving and using machines:
Nifedipine capsules 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 be more likely when you first start treatment, if you change medication, or if you have drunk alcohol.

Sodium content
This medicine contains less than 1mmol sodium (23mg) per capsule, this is to say essentially 'sodium free.'

3. HOW TO TAKE NIFEDIPINE CAPSULES

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

The capsules should be swallowed with water.

Adults:
The recommended starting dose is 5mg, every 8 hours. This may then be adjusted by your doctor, according to your body's response.

Your doctor may increase your dosage to 20mg, every 8 hours, if necessary.

Patients with liver problems or those on other medication will be carefully monitored by their doctor.

Patients with kidney problems will be given the normal recommended dosage.

Elderly patients:
Lower maintenance doses of nifedipine may be required.

Use in children and adolescents:
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.

If you experience any unexpected anginal pain soon after taking nifedipine, stop taking the medicine and tell your doctor immediately.

If you take more Nifedipine Capsules than you should:
If you take too many capsules you should contact your nearest hospital casualty department immediately. Take the remaining capsules and box with you. Taking too many capsules may cause your blood pressure to become too low and your heartbeat to 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 Nifedipine Capsules:
Tell your doctor at your next visit if you have missed a few doses. Do not worry. Take the missed dose as soon as you remember, waiting 12 hours before taking your next dose. Do not take more than your prescribed dose. Tell your doctor at your next visit if you have missed a few doses.

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

If you stop taking Nifedipine Capsules:
Consult your doctor before you stop taking nifedipine as your original symptoms may return if you stop taking it.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Nifedipine Capsules can have 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 Nifedipine capsules and seek urgent medical 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 Nifedipine capsules 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 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 multiforme or pemphigoid reactions.

Other side effects
If any of the following side-effects become troublesome, continue taking Nifedipine capsules but talk to your doctor immediately:
Common side effects
(*These may affect up to 1 in 10 people*)
- headache
- general feeling of being unwell
- constipation
- swelling, particularly of the ankle and legs

Uncommon side effects
(These may affect up to 1 in 100 people)
- stomach pain (*abdominal pain*)
- unspecific pain
- chills
- low blood pressure when standing up (symptoms include fainting, dizziness, light headedness, occasional palpitations, blurred vision and sometimes confusion)
- fainting
- faster or 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
- nose bleeds
- nasal congestion
- a feeling of dizziness or 'spinning' (*vertigo*)
- migraine
- 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

Rare side effects
(These may affect up to 1 in 1,000 people)
- pins and needles
- inflammation of the gums, tender or swollen gums, bleeding gums.
- itchy skin
- rash, hives
- changes in mood

Other side effects
(*Frequency not known: frequency cannot be estimated from the available data)*
- vomiting
- 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 (*hypoaesthesia*)
- insufficient blood flow to the brain
- sleepiness
- lethargy
- eye pain
- chest pain (*angina pectoris*)
- heartburn or indigestion (*gastroesophageal sphincter insufficiency*)
- decreased blood flow to your heart
- sensitivity to light (*photosensitivity allergic reaction*)
- small, raised areas of bleeding in the skin (*palpable purpura*)
- joint pain
- muscle pain
- shortness of breath (*dysponea*)
- flushing
- diarrhoea
- spider veins
- 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, 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 these capsules in a dry place below 25°C and protect them from light.

Do not use this medicine if you notice any defects such as split capsules.

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

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Nifedipine Capsules contain:
Nifedipine Capsules 5mg contain the active ingredient nifedipine at 5mg per capsule. The other ingredients are: povidone, polysorbate 80, saccharin sodium, menthol, tetrahydrofurfuryl alcohol-polyethyleneglycol ether, gelatin, glycerol 85%, titanium dioxide (E171), carmine red (E120), purified water.
Nifedipine Capsules 10mg contain the active ingredient nifedipine at 10mg per capsule. The other ingredients are: povidone, polysorbate 80, saccharin sodium, menthol, tetrahydrofurfuryl alcohol-polyethyleneglycol ether, gelatin, glycerol 85%, titanium dioxide (E171), carmine red (E120), purified water.

What Nifedipine Capsules look like and contents of the pack:
Nifedipine Capsules 5mg are shiny, oval, light red soft gelatine capsules. Plain practically odourless.
Nifedipine Capsules 10mg are shiny, oval, dark red soft gelatine capsules. Plain practically odourless.

Marketing Authorisation Holder:
Ennogen IP Ltd
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Manufacturer:
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This leaflet was last revised in July 2026.

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