Nifedipine 5 mg and 10 mg capsules

Package leaflet: Information for the user

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 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:
1. What Nifedipine is and what it is used for
2. What you need to know before you take Nifedipine
3. How to take Nifedipine
4. Possible side effects
5. How to store Nifedipine
6. Contents of the pack and other information

1. What Nifedipine is and what it is used for

Nifedipine is a selective calcium channel blocker. It slows the rate at which calcium flows into cells, and thus modifies the contraction of muscles, particularly heart muscle and causes a reduction in blood pressure.

Nifedipine is used:
• to prevent angina attacks in patients suffering from chronic stable angina.
• for the treatment of hypertension, in particular severe cases of essential hypertension in which other antihypertensive drugs have not been effective or caused intolerable side effects. Nifedipine may also be useful in treating patients with severe essential hypertension (hypertension which cannot be adequately treated with other antihypertensive drugs) who do not respond to treatment with diuretics or other antihypertensive agents and who are not candidates for surgery. Nifedipine may also be useful in treating patients during the acute treatment of Raynaud’s phenomenon, where poor blood circulation makes toes and fingers numb and pale.

2. What you need to know before you take Nifedipine

Do not take Nifedipine:
• if you are allergic to active substance(s) or any of the other ingredients of this medicine (listed in section 6) or other dihydropyridine calcium channel blockers, nicardipine, felodipine.
• if you have significant aortic stenosis (abnormal narrowing of the aortic valve in the heart)
• if you have unstable angina pectoris (chest pain)
• if you have a heart attack within the last month
• if you are currently having an acute angina (chest pain) attack
• if you are pregnant or are planning to become pregnant, or are breast-feeding
• if you are taking rifampicin (an antibiotic used to treat tuberculosis).
• if you have suffered a collapse of your blood circulation system (cardiovascular shock).
• if you experience increase in the blood pressure despite treatment (malignant hypertension).

Take special care with Nifedipine

Warnings and precautions
Talk to your doctor before taking Nifedipine if you:
• are diabetic
• have severe high or low blood pressure
• have poor cardiac reserve (a reduction in the ability of the heart to do work)
• are on dialysis and have very high blood pressure and low blood volume
• have liver problems. Your doctor may need to do some blood tests. You may also be given a lower dose of nifedipine.

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 nifedipine
• if you have chest pains after taking your first dose of nifedipine. 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. Nifedipine 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 have been shown to impair sperm function.

3. How to take Nifedipine

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 preferably with a glass of water.
The recommended dose is:
• Adults
  5 mg every 8 hours. The dose may be adjusted according to response up to 20 mg every 8 hours.
• Elderly
  A lower maintenance dose of Nifedipine may be required in the elderly.
• Children
  Nifedipine 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.

Other medicines and Nifedipine
Do not take Nifedipine if you are taking rifampicin (an antibiotic used to treat tuberculosis).
Tell your doctor or pharmacist if you are taking any other medicines that contain:
• aminoglycosides (antibacterial drugs)
• ketocnazole, itraconazole or fluconazole (anti-fungal drugs)
• fluoxetine or nefazodone (antidepressants)
• ketoconazole, itraconazole or fluconazole (anti-fungal drugs)
• quinidine or digoxin (for the heart), diltiazem (a heart drug), or any other drugs to control blood pressure.
• phenytoin, carbamazepine, valproic acid or phenobarbitone (for epilepsy).

4. Possible side effects

Side effects can occur. However, not everyone is affected. The following side effects may occur:
• Nifedipine may cause effects such as visual disturbances, drowsiness, and loss of weight.
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Tell your doctor if you experience:
• increase in the blood pressure
• if you have suffered a collapse of your blood circulation system (cardiovascular shock).
• if you experience increase in the blood pressure despite treatment (malignant hypertension).

5. How to store Nifedipine

Nifedipine should be stored in the original packaging and protected from light and freezing. Store in a cool dry place. Do not expose to direct sunlight.

6. Contents of the pack and other information

Nifedipine 5 mg and 10 mg capsules are light yellow capsules. The capsules contain:
• Nifedipine 5 mg and 10 mg capsules contain E1 10 (sunset yellow) which may cause allergic reactions.

Important information about some of the ingredients of Nifedipine
• Nifedipine capsules contain E1 10 (sunset yellow) which may cause allergic reactions.

Nifedipine with food, drink and alcohol
Do not take Nifedipine capsules with grapefruit juice, because this affects the amount of nifedipine which enters the bloodstream.

Driving and using machines
Nifedipine may cause effects such as visual disturbances, drowsiness and low blood pressure particularly at the start of treatment, on changing from another medication, or if taken in combination with alcohol; these effects can affect your ability to drive or operate machinery. If affected, do NOT drive or operate machinery.

Pregnancy, breast-feeding and fertility
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.

You may be able to use nifedipine capsules after week 20 of your pregnancy, but only after special consideration and agreement by your doctor.

Other medicines and Nifedipine
Do not take Nifedipine if you are taking rifampicin (an antibiotic used to treat tuberculosis).

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

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

Tell your doctor:
• if you are giving a urine sample. Nifedipine 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 have been shown to impair sperm function.

Other medicines and Nifedipine
Do not take Nifedipine if you are taking rifampicin (an antibiotic used to treat tuberculosis).

Tell your doctor or pharmacist if you are taking any other medicines that contain:
• aminoglycosides (antibacterial drugs)
• ketocnazole, itraconazole or fluconazole (anti-fungal drugs)
• fluoxetine or nefazodone (antidepressants)
• ketoconazole, itraconazole or fluconazole (anti-fungal drugs)
• quinidine or digoxin (for the heart), diltiazem (a heart drug), or any other drugs to control blood pressure.
• phenytoin, carbamazepine, valproic acid or phenobarbitone (for epilepsy).

Tell your doctor if you experience:
• increase in the blood pressure
• if you have suffered a collapse of your blood circulation system (cardiovascular shock).
• if you experience increase in the blood pressure despite treatment (malignant hypertension).

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

Tell your doctor:
• if you are giving a urine sample. Nifedipine 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 have been shown to impair sperm function.
If you take more Nifedipine than you should If you (or someone else) swallow a lot of the capsules all together, or if you think a child has swallowed any of the capsules, contact your nearest hospital casualty department or your doctor immediately. An overdose is likely to cause severe low blood pressure and very fast heart rate or very slow heart rate. Additional signs include nausea, vomiting, drowsiness, dizziness, confusion, tiredness, flushing and unconsciousness.

Please take this leaflet, any remaining capsules and the container with you to the hospital or doctor so that they know which capsules were consumed.

If you forget to take Nifedipine
If you forget to take a capsule, take one as soon as you remember, unless it is nearly time to take the next one. Do not take a double dose to make up for a forgotten dose.

If you stop taking Nifedipine
Do not stop taking your medicine without talking to your doctor first even if you feel better. If you have any further questions on the use of 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.

If the following happens, stop taking the capsules and tell your doctor or go to the casualty department at your nearest hospital:
- an allergic reaction (swelling of the lips, face or neck leading to severe difficulty in breathing; skin rash or nettle rash)
- a skin reaction or blistering / peeling of the skin and/or mucosal reactions (in the mouth/nose or at the penis/vagina) (Epidermal Necrolysis)
- an allergic reaction (swelling of the lips, face or neck leading to severe difficulty in breathing; skin rash or nettle rash)
- 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).

This is a very serious but rare side effect. You may need urgent medical attention or hospitalisation.

Talk to your doctor immediately if you get increasing chest pain shortly after taking Nifedipine.

The following side effects have been reported at the approximate frequencies shown:

Common: (may affect up to 1 in 10 people )
- headache
- swelling of the hands, feet and ankles
- widening of blood vessels (vasodilatation)
- constipation
- general feeling of being unwell

Uncommon: (may affect up to 1 in 100 people)
- anxiety or nervousness
- sleep disorders
- vertigo (a feeling of dizziness or “spinning”)
- migraine
- dizziness
- shaking
- agitation
- problems with sight
- irregular heartbeats (palpitations)

Unsuspected: (may affect up to 1 in 1,000 people)
- chest pain
- nose bleeds
- rash or skin reaction
- increased risk of skin cancer
- heartburn or indigestion, diarrhoea or other stomach problems
- temporary increase in certain liver enzymes
- reddening of the skin
- sweating
- muscle cramps
- joint swelling
- increase in the need to pass water (urinate)
- painful or difficult urination
- inability to achieve or maintain erection (impotence)
- unexplained pain
- chills
- lethargy

Rare: (may affect up to 1 in 1,000 people)
- itching, nettle rash
- pins and needles
- inflammation of the gums, tender or swollen gums, bleeding gums.

Not known: (frequency cannot be estimated from the available data)
- a more severe decrease in a specific class of white blood cell (agranulocytosis)
- a reduction in the number of white blood cells (leucopenia)
- sensitivity to light (photosensitivity allergic reaction)
- small, raised areas of bleeding in the skin (palpable purpura)
- increased blood sugar (hyperglycaemia)
- decreased skin sensitivity (hyposensitivity)
- drowsiness (somnolence)
- eye pain
- chest pain (angina pectoris)
- shortness of breath (dyspnoea)
- vomiting
- heartburn or indigestion (gastroesophageal sphincter insufficiency)
- yellowing of the whites of the eyes or skin (jaundice)
- joint pain
- muscle pain
- excess collection of watery fluid in the lungs

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 at: www.mhra.gov.uk/yelllowcard

By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Nifedipine

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

Store in the original package. Do not store above 25°C. Do not use this medicine after the expiry date which is stated on the outer packaging. 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 Nifedipine capsules contain:
- The active ingredient is either 5 mg or 10 mg of nifedipine.
- The other ingredients are polyethylene glycol 400, glycerol (E422), peppermint oil and sodium saccharin (E954). The capsule shell contains gelatin, glycerol (E422), and the colours titanium dioxide (E171), sunset yellow (E110) and erythrosine (E127). The white printing ink contains propylene glycol, titanium dioxide (E171), polyvinyl acetate phthalate and polyethylene glycol.

What Nifedipine capsules look like and contents of the pack:
- Nifedipine 5 mg capsules are opaque, oval, soft gelatin capsules containing an orange liquid. Overprinted 2L3 in white.
- Nifedipine 10 mg capsules are opaque, oblong, soft gelatin capsules containing an orange liquid. Overprinted 2L4 in white.
- The products are available in packs of 7, 10, 14, 21, 28, 30, 60, 60, 90, 100, 110, 112, 120, 150, 160 and 168. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder and company responsible for manufacture is Teva UK Limited, Eastbourne, BN22 9AG.

This leaflet was last revised: July 2016

PL 00289/0745-6