

Nifedipine 5mg and 10mg Capsules

(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 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 | 4 Possible side effects |
| 2 What you need to know before you take Nifedipine | 5 How to store Nifedipine |
| 3 How to take Nifedipine | 6 Contents of the pack and other information |

1 What Nifedipine is and what it is used for

Nifedipine Capsules contain the active substance Nifedipine. This belongs to a group of medicines known as calcium channel blockers. These work by opening up the blood vessels and increasing the flow of blood through them.

Nifedipine is used:

- To prevent attacks of chest pain (angina).

Angina is chest pain caused by a narrowing of the arteries in the heart muscle. Chronic stable angina is a pattern of attacks of chest pain that are predictable and happen under certain conditions such as after exercise, stress or in cold weather.

- To treat high blood pressure (hypertension)

2 What you need to know before you take Nifedipine

DO NOT take Nifedipine if:

- You are allergic (hypersensitive) to Nifedipine or any of the other ingredients of this medicine (See Section 6 "Contents of the pack and other information")
- You are allergic (hypersensitive) to other similar medicines (known as dihydropyridine) such as Nicardipine, Amlodipine, Felodipine, Isradipine, Lacidipine or Nimodipine
- You have a severe problem with your heart which causes collapse and a sudden fall in your blood pressure
- You suffer from narrowing of the valve in your heart (aortic stenosis)
- You have a sudden attack of chest pain (angina) or chest pain even at rest, which increases in severity (unstable angina)
- You have suffered a heart attack within last month (acute myocardial infarction)
- You have a history of heart attacks (myocardial infarction)
- You are taking the medicine Rifampicin, a medicine used to treat tuberculosis (See "Other medicines and Nifedipine" section)
- You suffer from porphyria (a rare disease of the blood pigment)
- Your blood pressure continues to rise despite treatment (malignant hypertension)

Warnings and precautions

Talk to your doctor before taking Nifedipine if:

- You suffer from very low blood pressure, which causes dizziness or fainting on standing up (severe hypotension). Your blood pressure may be decreased further by this treatment
- You have heart problems where your heart cannot cope with increased strain (poor cardiac reserve)
- You have liver problems
- You are diabetic The treatment for your diabetes may need to be adjusted
- You are taking another medicine to treat high blood pressure, such as beta-blockers (See "Other medicines and Nifedipine" section)
- You experience chest pains when you **first** start taking Nifedipine, contact your doctor **immediately**
- Your chest pain (angina) gets worse (comes on more often or more severely) over a matter of hours or days
- You are changing from beta-blockers to Nifedipine as the dose of your beta-blocker should be reduced gradually, preferably over 8 - 10 days
- You are given magnesium sulphate injections and you are pregnant [may cause a severe fall in blood pressure] (See "Other medicines and Nifedipine" section)
- You are on kidney dialysis and have a very high blood pressure, which continues to rise despite treatment and have a low blood volume. You might experience a sudden drop in blood pressure when you take this medicine
- You are taking the following medicines as your blood pressure should be monitored and a reduction of Nifedipine may need to be considered: (See "Other medicines and Nifedipine" section)
 - o Erythromycin, quinupristin,dalfopristin (used to treat bacterial infections)
 - o Ritonavir (used to treat HIV)
 - o Ketoconazole (used to treat fungal infections)
 - o Fluoxetine and Nefazodone (used to treat depression)
 - o Valproic acid (used to treat convulsions and epilepsy)
 - o Cimetidine (used to treat stomach ulcers)
- You are pregnant or breast-feeding. (See "Pregnancy and breast-feeding" section)

Other medicines and Nifedipine

Tell your doctor or pharmacist if you are taking,

have recently taken or might take, any other medicines, including medicines obtained without a prescription. This includes herbal medicines.

Nifedipine **should not be taken** with the following:

- Rifampicin, used to treat tuberculosis

Medicines which may interact with or be affected by Nifedipine:

- Cimetidine, used to treat ulcers and reduce stomach acidity
- Macrolide antibiotics, used to treat bacterial infections e.g. Erythromycin, Azithromycin
- Medicines used to treat HIV infections e.g. Ritonavir
- Medicines used to treat fungal infections e.g. Ketoconazole
- Fluoxetine and Nefazodone, used to treat depression
- Quinupristin/dalfopristin, an antibiotic used to treat serious bacterial infections
- Phenytoin, Valproic Acid and Carbamazepine used to treat seizures and epilepsy
- Cisapride, used to treat heart burn
- Phenobarbital, used to treat insomnia or anxiety
- Medicines used to treat high blood pressure, e.g. Atenolol (beta-blocker), Diltiazem (calcium channel blocker), Lisinopril (ACE inhibitors), Indapamide (diuretics), Tadalafil (PDE5 inhibitors), Methyldopa (alpha-adrenergic agonists), Losartan (angiotensin receptor antagonists)
- Quinidine, used to treat irregular heart rhythms
- Tacrolimus, used to prevent the rejection of transplanted organs
- Digoxin, used to treat heart failure and symptoms of shortness of breath when lying flat
- Magnesium sulphate injections during pregnancy (may cause a severe fall in blood pressure)
- Urine tests: Nifedipine may interfere with the results of certain urine tests

Nifedipine with food and drink

Do not drink grapefruit juice or eat grapefruit whilst taking this medicine. Grapefruit juice can increase the amount of Nifedipine in the blood. This effect can last at least 3 days after having grapefruit juice.

Nifedipine and alcohol

During treatment with Nifedipine, it is advisable not to drink alcohol as this may cause you to feel sick, dizzy, extremely tired or suffer headaches (see "Driving and using machines section").

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.

Pregnancy

If you are pregnant you should not take Nifedipine. Nifedipine should only be taken by pregnant women suffering from severely high blood pressure where standard treatment has failed.

Breast-feeding

If you are breast-feeding, you must not take Nifedipine. You should stop breast-feeding before taking this medicine. Nifedipine has been reported to be excreted in human milk and the effects are not known

Fertility

In vitro fertilisation:
If you are a man and have been repeatedly unable to father a child by in vitro fertilisation (IVF), and no other explanation has been found, it is possible that your sperm function may be affected by medicines such as Nifedipine.

Driving and using machines

Nifedipine make some people feel dizzy, faint, extremely tired or have visual problems. If this occurs, do not drive or operate machinery.

These symptoms are more likely to occur when you first start treatment, change medication or if you have drunk alcohol (see "Nifedipine and alcohol" section).

Nifedipine contains glycerin, which may cause headaches, stomach upset or diarrhoea.

3 How to take Nifedipine

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

- These capsules are for oral administration
- Nifedipine Capsules should be swallowed whole with a little water
- **Do not drink** grapefruit juice or eat grapefruit whilst being treated with this medicine

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The recommended dose is:

Adults:

The recommended starting dose is 5mg every 8 hours. Your doctor may adjust the dosage to 20mg every 8 hours.

Elderly:

Lower doses may be required for the elderly. Your doctor will set the appropriate dosage to your specific condition.

Patients with liver problems:

Patients with liver problems should be closely monitored by their doctor

Use in children:

Nifedipine Capsules are **not** recommended for use in children and adolescents below 18 years of age, because the safety and efficacy of Nifedipine has not been established.

If you take more Nifedipine than you should

If you accidentally take more capsules than you should contact your doctor or hospital **immediately**. Take any remaining capsules or this leaflet with you so the medical staff know exactly what you have taken.

The symptoms of overdose include: very low blood pressure, fast/slow heart beat, increased blood sugar level, increased acidity in the blood, high/low levels of potassium in the blood, heart problems, drowsiness, dizziness, confusion, feeling or being sick, lack of energy (lethargy), flushing, low blood oxygen levels, a lack of consciousness to point of coma and excess collection of watery fluid in the lungs.

If you forget to take your Nifedipine

Take the normal dose as soon as you remember. **Do not** take a double dose to make up for a forgotten dose.

If you stop taking Nifedipine

Do not stop taking your capsules suddenly as your condition may get worse. Consult your doctor first.

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.

Stop taking Nifedipine and tell your doctor immediately if you develop the following symptoms:

- allergic reaction such as skin rash, itching, swollen lips
- difficulty breathing or dizziness (anaphylactic reaction)
- swelling of the face or throat, including swelling of the larynx, which may result in a life-threatening outcome
- swelling of the deeper layers of the skin caused by a build-up of fluid (angioedema)
- severe blistering of the skin, mouth, eyes and genitals (Toxic Epidermal Necrolysis) [TEN]
- chest pain (frequently occurs at the start of treatment)

Common side effects (may affect up to 1 in 10 people):

- headache
- swelling of parts of the body, particularly of the ankles (oedema)
- flushing (redness of the face and neck)
- constipation
- widening of blood vessels (vasodilatation). (A distinct fall in blood pressure can occur in dialysis patients with malignant hypertension [very high blood pressure that comes on suddenly and quickly] and hypovolaemia [severe blood and fluid loss making the heart unable to pump enough blood to the body] as a result of vasodilation)
- feeling unwell

Uncommon side effects (may affect up to 1 in 100 people):

- feeling anxious
- sleep problems
- feeling of dizziness or 'spinning' (vertigo)
- severe headache (migraine)
- shaking (tremors)
- sight disturbances
- faster heart beat (tachycardia)
- feeling your heart beat (palpitations)
- low blood pressure, which may cause light headedness, fainting or dizziness, especially when going from sitting or lying position to standing up
- fainting (syncope)
- nasal congestion
- nose bleed
- stomach or abdominal pain
- indigestion
- feeling bloated/wind (flatulence)
- dry mouth
- feeling sick (nausea)
- reddening of the skin
- muscle cramps
- joint swelling
- painful or difficult urination (dysuria)
- increased production of urine (polyuria)
- inability to achieve or maintain an erection
- general, unspecific pain
- feeling cold
- temporary increase in liver enzymes (detected through blood test)

Rare side effects (may affect up to 1 in 1,000 people):

- burning, tingling or numbness in the hands or feet (paraesthesia) or abnormal sense of touch (dysaesthesia)
- general weakness and loss of strength and energy (lethargy)

- enlargement of the gums (gingivitis/gingival hyperplasia) [reversible following withdrawal of this medicine]
- itching (pruritus)
- skin rashes with the formation of wheals (urticaria)
- rashes
- increased need to pass water (urine)

Not known (frequency cannot be estimated from the available data):

- more prone to infections. This may be due to a severe reduction in number of white blood cells (agranulocytosis, leucopenia)
- increase in blood sugar levels (hyperglycaemia)
- decreased skin sensitivity to pain or touch (hypoesthesia)
- feeling sleepy or drowsy (somnolence)
- eye pain
- chest pain (angina)
- breathlessness
- being sick (vomiting)
- a solid mass of indigestible material that collects in your digestive tract, sometimes causing a blockage (bezoar)
- difficulty swallowing (dysphagia)
- abdominal pain caused by obstruction of the gut or ulcers in the gut
- heartburn or indigestion
- yellowing of the skin or whites of the eyes (jaundice)
- abnormal sensitivity of the skin to sunlight (photosensitivity)
- skin rash caused by small blood vessels bleeding into the skin (palpable purpura)
- muscular pain (myalgia), joint pain (arthralgia)
- in older men, excessive enlargement of the breast (gynecomastia) [reversible following withdrawal of this medicine]
- build up of bile acids in the bloodstream causing persistent itch (cholestasis) [reversible following withdrawal of this medicine]
- depression

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 internet at (www.mhra.gov.uk/yellowcard). By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Nifedipine

- Keep out of the sight and reach of children.
- Store in the original package in order to protect from heat, light and moisture.
- Do not use this medicine after the expiry date which is stated on the carton/blister 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 to protect the environment.

6 Contents of the pack and other information

What Nifedipine contains:

Each 5mg capsule contains 5mg of Nifedipine
Each 10mg capsule contains 10mg of Nifedipine

The other ingredients are: polyethylene glycol 400, glycerin 98%, menthol, saccharin sodium and purified water. Capsule shell constituents: gelatin, glycerin 98%, black iron oxide (E172), red iron oxide (E172), yellow iron oxide (E172), purified water and titanium dioxide (E171) (titanium dioxide E171 only applicable to the 5mg capsules).

What Nifedipine looks like and contents of the pack:

Nifedipine 5mg capsules: oval, dark brown, soft gelatin capsule. The capsules are size 3.
Nifedipine 10mg capsules: oblong, dark brown, soft gelatin capsule. The capsules are size 6.

Nifedipine is available in:

Nifedipine capsules are available in packs of 20, 28, 56, 84, 100 or 500 capsules
Not all pack sizes may be marketed.

Marketing Authorisation Holder:

Activase Pharmaceuticals Limited,
11 Boumpoulinas
Nicosia 1060
Cyprus



Manufacturer:

Tillomed Laboratories Limited,
3 Howard Road,
Eaton Socon, St Neots,
Cambridgeshire,
PE19 8ET
United Kingdom.

Product Licence Numbers:

Nifedipine 5mg Capsules: PL 28444/0223
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