

FENAMON TABLET

Nifedipine (10mg)

In this leaflet:

1. What FENAMON is used for
2. How FENAMON works
3. Before you use FENAMON
4. How to use FENAMON
5. While you were using it
6. Side effects
7. Storage and disposal of FENAMON
8. Product description
9. Manufacturer and Product Registration Holder
10. Date of revision

What FENAMON is used for

FENAMON can be used to reduce high blood pressure, to relieve chest pain (angina) and to treat Raynaud's phenomenon.

How FENAMON works

Nifedipine belongs to a group of medicines called calcium channel antagonists; these relax and expand blood vessels.

In high blood pressure, nifedipine works by widening the blood vessels. This creates less resistance to the blood flow, and results in lower blood pressure, which in turn reduces the strain on your heart. In angina, nifedipine works by opening up the arteries supplying the heart muscle and this allows more blood and oxygen to reach the muscle, decreasing the chances of angina occurring when extra strain is placed upon the heart.

Before you use FENAMON

When you must not use it

Do not take FENAMON if:

- You are allergic to nifedipine or any of the other ingredients of this medicine or to any other similar drugs (known as dihydropyridines); if you are unsure about this, ask your doctor
- You have unstable angina (severity or frequency of your angina has rapidly worsened over a matter of hours or days)
- You have ever experienced a collapse in the past which was caused by a heart problem (cardiogenic shock), during which you would have become breathless, pale and had a

cold sweat and dry mouth

- For secondary prevention of a heart attack
- For the treatment of a heart attack or within one month of a heart attack
- You have been told that you have a narrowing (stenosis) of the aortic valve of the heart
- Your blood pressure is continuing to rise despite treatment. This is a condition known as malignant hypertension
- You are taking the antibiotic rifampicin

Pregnancy and breast-feeding

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. FENAMON is not recommended in pregnancy and breast feeding.

Before you start to use it

Before taking any of this medicine, please tell your doctor:

- if you experience chest pains after taking your FIRST dose of FENAMON
- if you suffer from low blood pressure
- if you notice increased breathlessness or swelling of the ankles, or if your heart condition gets worse
- if you have a heart condition where your heart cannot cope with increased strain (poor cardiac reserve)
- if you have a liver disease
- if you are a diabetic
- if you are taking other drugs to treat high blood pressure

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription, especially:

- rifampicin, an antibiotic
- other drugs to treat high blood pressure
- cimetidine, to treat stomach ulcers
- digoxin, diltiazem, quinidine or beta-blockers, which are used to treat heart conditions
- phenytoin, a drug to treat fits

- antibiotics such as quinupristin, dalfopristin,
- theophylline
- cisapride, a drug used to treat reduced movements of the gullet and stomach
- the antibiotic erythromycin, or the anti-fungals, ketoconazole, itraconazole or fluconazole
- the HIV protease inhibitors indinavir, ritonavir, saquinavir
- the antidepressant drugs fluoxetine and nefazodone
- tacrolimus, an immunosuppressant used to prevent the rejection of transplant organs
- carbamazepine and valproic acid, which are both used for the treatment of fits
- the barbiturate, phenobarbital, used primarily to treat insomnia and anxiety

How to use FENAMON

How much to use

The dosages given are general, doctors sometimes prescribe different doses, you should follow your doctor's instructions.

Initial dose is 10mg (swallowed whole) 3 times a day orally. The dose can be increased to a maximum of 60mg daily.

Elderly:

Lower doses of this medicine may be recommended by your doctor in the elderly.

Children

This medicine is not recommended for use in children.

Kidney problems:

In patients with renal impairment dosage adjustment is not required.

Liver problems:

Patients with liver dysfunction require careful monitoring and dose titration.

When to use it

Always take FENAMON exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. Always read the printed information leaflet, if possible, before beginning treatment.

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How long to use it

Do not stop taking FENAMON unless your doctor tells you to, however well you feel.

If you forget to use it

- If you forget to take FENAMON, take it as soon as you remember. If, however, you are close to the time for the next dose, wait until then and take your next dose.
- Do not take a double dose to make up for the missed dose. Do not take more medicine in one day than your doctor tells you to.

If you use too much (overdose)

- Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.
- Always take the medicine container with you, so they know what you have taken.

While you are using it

Things you must do

- Tell all your doctors, dentists and pharmacists treating you that you are taking FENAMON.
- Tell your doctor immediately if you become pregnant while taking this medication.

Things you must not do

- Do not stop taking the medicine unless advised by your doctor.
- Do not take any new medicines without consulting your doctor.
- Do not give FENAMON to anyone else, even if they have the same symptoms or condition as you.

Things to be careful of

- Nifedipine must not be taken with grapefruit juice.
- You are advised to avoid alcohol whilst taking this medicine. Discuss this with your doctor if you have any questions.

Driving and using machines

FENAMON tablets may make you feel drowsy and/or dizzy. Make sure you are

not affected before you drive or operate machinery.

FENAMON contains Lactose Monohydrate and Orange Lake.

If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicinal product

Orange Lake may cause allergic reactions.

Side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. FENAMON may occasionally cause side effects when you first start taking this medicine.

If you experience chest pain after taking your first dose of FENAMON, contact your doctor before you take the next dose. Your doctor may wish to change your treatment.

Tell your doctor IMMEDIATELY if the medicine causes swelling of lips, tongue or difficulty in breathing. If a nettle rash or other spots develop this may be due to an allergy to the medicine. Stop taking it and tell your doctor as soon as possible.

The most commonly reported side effects are:

- headache,
- swelling of ankles, feet or fingers – not associated with heart failure or weight gain,
- widening of blood vessels (vasodilatation),
- dizziness,
- nausea

Other less commonly reported side effects:

- pain particularly in the stomach area (abdomen)
- indigestion
- diarrhoea
- constipation
- vomiting
- flatulence
- enlarged abdomen
- dry mouth
- irregular heartbeat (palpitations)

- yellowish discolouration of the whites of eyes, skin and mucous membranes
- swelling
- pain in the chest or legs
- low blood pressure when rising to a standing position (symptoms include fainting, dizziness, light headedness, occasional palpitations, blurred vision and sometimes confusion)
- low blood pressure leading to irregular heartbeat, fast heartbeat (tachycardia)
- an allergic reaction that may become severe
- muscle cramp
- reddish/purplish skin discolouration
- itching
- hives, rash, blistering of skin when exposed to sunlight
- difficulty in sleeping
- sleepiness
- tremor, agitation
- mood changes, anxiety reactions
- increased physical sensitivity (hyperaesthesia)
- tingling or numbness (paresthesia)
- sweating
- liver function test abnormalities
- fainting
- excessive passage of urine,
- erectile problems
- difficulty in breathing,
- gum problems
- loss of appetite
- raise in blood sugar,
- abnormal vision
- enlargement of men's breasts (gynecomastia)

If you experience any of these effects or other effects that you think are caused by FENAMON, tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

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Storage and disposal of FENAMON

Storage

- Keep out of the reach and sight of children.
- Store below 30°C in the original package in a dry place, protected from light.

Disposal

- Do not use after the expiry date stated on the carton and blister.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product description

What it looks like

FENAMON tablets are presented as yellow, round, flat tablets embossed "MC" with diameter 8 mm

Ingredients

- Active ingredient

FENAMON 10mg tablets contain 10mg Nifedipine

- Inactive ingredients

Other ingredients in the tablet includes povidone, lactose monohydrate, microcrystalline cellulose, sodium starch glycolate, silica colloidal anhydrous, quinolone yellow lake (E104), sunset yellow lake (E110), silica colloidal anhydrous and magnesium stearate.

MAL No.

MAL19861587AZ

Manufacturer

MEDOCHEMIE LTD (Central Factory),
1-10, Constantinopouleos Street, 3011
Limassol, Cyprus

Product Registration Holder

KOMEDIC SDN BHD, 4, Jalan PJS
11/14, Bandar Sunway, 46150 Petaling
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