

Package leaflet: Information for the user

Nifed Retard 20 mg Modified Release Tablets

Active substance: 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. 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.

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



1 What Nifed Retard is and what it is used for

Nifed Retard contains nifedipine which belongs to a group of medicines called calcium antagonists.

- Nifed Retard is used to treat:
- Mild to moderate high blood pressure
 - A certain type of chest pain called angina pectoris

If you suffer from high blood pressure Nifed Retard works by relaxing blood vessels, so that blood passes through them more easily.

If you suffer from angina Nifed Retard works by improving blood supply to the heart muscle which then receives more oxygen and as a result chest pain is prevented. Nifedipine does not provide immediate relief of chest pain from angina.

2 What you need to know before you take Nifed Retard

- Do not take Nifed Retard** if you have any of the following conditions:
- allergy to nifedipine (active substance) or to any of the ingredients (listed in section 6).
 - allergy to calcium antagonists known as dihydropyridines (the group of medicines that nifedipine belongs to)
 - have insufficient blood supply to your tissues, e.g. caused by severe heart troubles (cardiogenic shock)
 - are within 4 weeks of a heart attack
 - narrowing of the aortic heart valve (aortic stenosis)
 - unstable angina
 - have a sudden angina attack
 - are taking rifampicin, an antibiotic
 - your blood pressure continues to rise despite treatment (malignant hypertension)
 - are pregnant, are trying to become pregnant or are breastfeeding

- Warnings and precautions**
- Talk to your doctor or pharmacist before taking Nifed Retard
- if you have low blood pressure
 - if you have reduced heart function
 - if you have diabetes
 - If you have impaired liver function
 - if you are on dialysis

If you experience chest pains within 1-4 hours of taking your first dose of Nifed Retard, contact your doctor before you take the next dose. Your doctor may wish to change your treatment.

If you are male and have been unsuccessful in fathering a child by in vitro fertilisation please contact your doctor. Medicines like Nifed Retard may impair sperm count.

Nifed Retard may interfere with the results of certain urine tests. If you have given a urine sample, inform the person responsible that you are taking this medicine.

Other medicines and Nifed Retard

Nifed Retard and other medicines interact with each other.

It is therefore important to tell your doctor if you take any of the following medicines:

- **Medicines to treat high blood pressure**, e.g. beta-blockers. Nifed Retard may enhance the effects

- of these medicines.
- **Magnesium sulphate injections during pregnancy.**
- **Itraconazole, ketoconazole, fluconazole (antifungal medicines)** may intensify the effect of Nifed Retard.
- **Rifampicin (antibiotic)** may reduce the effect of Nifed Retard.
- **Indinavir, nelfinavir, ritonavir, saquinavir, amprenavir (to treat HIV)** may intensify the effect of Nifed Retard.
- **Carbamazepine, phenobarbitone, phenytoin (anti-epileptics)** may reduce the effect of Nifed Retard.
- **Valproic acid (anti-epileptic)** may intensify the effect of Nifed Retard.
- **Cisapride (stomach medicine)** may intensify the effect of Nifed Retard.
- **Quinupristin/dalfopristin (antibiotic)** may intensify the effect of Nifed Retard.
- **Tacrolimus (immunosuppressant)** Nifed Retard may intensify the effect of this medicine.
- **Quinidine, digoxin (heart medicines)** Nifed Retard may intensify the effect of these medicines.
- **Cimetidine (stomach ulcer medicine)** may intensify the effect of Nifed Retard.
- **Erythromycin (antibiotic)** may intensify the effect of Nifed Retard.
- **Nefazodone, fluoxetine (antidepressants)** may intensify the effect of Nifed Retard.
- **Ginkgo biloba (herbal product)** may intensify the effect of Nifed Retard.

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

Nifed Retard with food and drink

You can take Nifed Retard independently of food. You should not take this medicine with grapefruit juice.

Pregnancy and breastfeeding

If you are pregnant or become pregnant during treatment, do not take Nifed Retard unless specifically prescribed by your doctor.

If you are breastfeeding, do not take Nifed Retard. Please contact your doctor.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Be careful if you drive or operate machinery if you take this medicine. Nifed Retard may not directly affect your ability to drive or operate machinery. However, side effects such as dizziness may interfere with this ability, particularly together with alcohol.

Nifed Retard contains lactose monohydrate

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

3 How to take Nifed Retard

Always take Nifed Retard exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Dosage

Adults

You may be given a lower strength tablet initially to allow your doctor to monitor your response. The usual maintenance dose is 1 tablet every 12 hours. If necessary, your doctor may increase the dose to a maximum of 60 mg every 24 hours.

Children and adolescents

Nifed Retard 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.

Elderly patients

Follow your doctor's instructions.

Patients with reduced kidney function

The normal dosage is recommended. Follow your doctor's instructions.

Patients with reduced liver function

Your doctor may want to start your treatment on a low dose and increase it with careful monitoring.

Method of administration

Swallow the tablets whole with a glass of water; you can take them with or without food. You should not take this medicine with grapefruit juice. This medicine is for oral use only.

If you take more Nifed Retard than you should contact your doctor, an emergency department or a pharmacy if you have taken more Nifed Retard than recommended in the information leaflet or more than your doctor has prescribed.

An overdose can cause severe low blood pressure, your heartbeat to speed up or slow down, your blood sugar level to increase, low blood oxygen levels, an increase in the acidity of your blood and disturbances in consciousness, possibly leading to unconsciousness.

If you forget to take Nifed Retard

Take your normal dose immediately and continue taking your tablets as prescribed, waiting 12 hours before taking your next dose. Do not take a double dose to make up for a missed dose.

If you stop taking Nifed Retard

Do not stop taking Nifed Retard without talking to your doctor.

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 you notice:

- an allergic reaction that may become severe and may result in life-threatening shock
 - other allergic reactions causing swelling of the face, lips, tongue and/or throat, which may result in a life-threatening outcome
 - mild to moderate allergic reactions
- contact your doctor immediately and do not take the next dose.

Common: may affect up to 10 people

- headache
- flushing
- constipation
- feeling unwell
- swelling, particularly of the ankles and legs

Uncommon: may affect up to 100 people

- anxiety
- sleep disorders
- stomach pain
- nausea
- dry mouth
- indigestion
- wind (flatulence)
- transient increase in liver enzymes
- reddening of the skin
- muscle cramps
- joint swelling
- increased need to urinate

- painful urination
- uncontrolled shaking (tremor)
- sensation of spinning or whirling motion (vertigo)
- migraine
- dizziness
- problems with your eyesight (visual disturbance)
- a fast heartbeat
- quick and strong heartbeat (palpitations)
- low blood pressure
- fainting
- nasal congestion
- nose bleed
- impotence
- unspecific pain
- chills

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

- itching
- hives
- rash
- pins and needles
- an unpleasant abnormal sensation
- swollen gums

Not known: frequency cannot be estimated from the available data

- lowered white blood cell count
- high blood sugar levels
- reduction in skin sensitivity to pain or touch
- drowsiness or sleepiness
- eye pain
- chest pain
- breathing problems
- vomiting
- difficulty swallowing
- yellow discolouration of the skin
- a serious skin reaction (toxic epidermal necrolysis)
- allergic reaction to sunlight
- purplish - red spots
- muscle pain
- joint pain
- worsening of a condition involving severe muscle weakness (myasthenia gravis)

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

5 How to store Nifed Retard

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 carton and blister after 'EXP'. The expiry date refers to the last day of that month.

Do not store above 25°C. Store in the original package in order to protect from moisture and light. The tablets should only be removed from the blister strip when you are about to take them.

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 Nifed Retard contains:

- The active substance is nifedipine. Each tablet contains 20 mg of nifedipine.
- The other ingredients are polysorbate 80, maize starch, lactose monohydrate, microcrystalline cellulose, magnesium stearate, macrogol 4000, hypromellose, titanium dioxide (E171) and red ferric oxide (E172).

What Nifed Retard looks like and the contents of the pack

A pink to light red, round and slightly biconvex tablet.

Your tablet comes in

- Blister packs of 10, 20 and 100 tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturers

Marketing Authorisation Holder:
Rowex Ltd., Bantry, Co. Cork, Ireland

Manufacturers:

Salutas Pharma GmbH, Otto-von-Guericke Allee 1,
39179 Barleben, Germany
Rowa Pharmaceuticals Ltd., Bantry, Co. Cork, Ireland

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