**Nifedipine retard 30 mg and 60 mg prolonged-release tablets**

**Nifedipine**

Please read the entire leaflet carefully before using this medicine because it contains important information for you.

**What is nifedipine retard and what is it used for?**

**Operation:** This medicine contains the active ingredient nifedipine. Nifedipine belongs to a group of substances known as calcium antagonists. Nifedipine widens blood vessels, improving blood flow to the heart and limbs, and lowering blood pressure.

Nifedipine is slowly absorbed into the blood from the tablets. This reduces the likelihood of side effects and extends the duration of action. This medicine only needs to be taken once a day.

**Application:** High blood pressure: The doctor has diagnosed high blood pressure and has prescribed this medicine to lower blood pressure. Because high blood pressure often has no noticeable symptoms, the effectiveness of the treatment can only be determined by measuring blood pressure.

**Chronic chest pain:** The doctor has prescribed this medicine for the treatment of chronic chest pain caused by a lack of oxygen in the heart muscle (angina pectoris). Inform your doctor if the chest pain does not improve with the treatment.

**When should you not use this medicine or take extra precautions?**When should you not use this medicine?

* If you are allergic to any of the substances in this medicine.
* In case of very low blood pressure (hypotension).
* In a state of shock.
* If you have a specific stoma (Kock pouch).
* When using rifampicin (a medication for certain infectious diseases).

When should you take extra precautions with this medicine?

Contact your doctor or pharmacist before using this medicine if:

* This medicine should not be used during pregnancy unless your medical condition requires it (see Pregnancy section).
* If you are breastfeeding, the use of this medicine is not recommended.
* In case of diarrhea; the duration of action may be reduced.
* If you have a narrowing of the gastrointestinal tract. This medicine should not be used in this case. In very rare cases, intestinal concretions may form. Intestinal concretions are accumulations of unexcreted tablets, which may sometimes require surgical removal. Cases of obstruction have also been described in patients who did not previously have gastrointestinal disorders.
* If you need to undergo an X-ray examination; this medicine can affect the results of X-ray examinations using barium sulfate. Therefore, inform your healthcare provider about the use of this medicine before such an examination.
* If your liver function is insufficient, your doctor may reduce the dose in severe cases (see section 3).
* When you experience persistent, severe chest pain (angina pectoris). This is the result of rapid absorption of nifedipine into the bloodstream and a sudden drop in blood pressure. In such a case, immediately notify your treating physician and discontinue the treatment with this medicine.
* If the pumping function of your heart is reduced (decompensatio cordis). This medicine can further deteriorate an already reduced pumping function of the heart. If you become tired more quickly (e.g., when climbing stairs), this may be a sign of reduced pumping function.
* If you have a severe narrowing of the aorta (aortic stenosis).
* If you previously experienced the sensation of "dead" fingers or toes (ischemia), there is a possibility that this condition may worsen with the use of this medicine.

**Children and adolescents up to 18 years old**This medicine is not recommended for use in children and adolescents up to 18 years old because there is limited data on its safety and effectiveness in this group.

**Are you taking any other medicines?**Some medications can affect Nifedipine retard or be affected by Nifedipine retard.

If you are taking or have recently taken other medicines, or if you may use other medicines in the near future, please inform your doctor or pharmacist.

* The following medications can reduce the blood pressure-lowering effect of nifedipine:
* Rifampicin, a medication for the treatment of infectious diseases .
* Phenytoin, carbamazepine, and phenobarbital, medications for the treatment of epilepsy.
* The following medications can enhance the blood pressure-lowering effect of nifedipine:
* Blood pressure-lowering agents such as diuretics, beta-blockers, ACE inhibitors, AT1 receptor antagonists, other calcium antagonists, alpha-blockers, and methyldopa.
* Medications for the treatment of erectile dysfunction, as these medications also lower blood pressure (known as phosphodiesterase-5 inhibitors).
* Medications for the treatment of infectious diseases such as erythromycin and other macrolide antibiotics.
* Medications for the treatment of AIDS, such as ritonavir and similar medications.
* Medications for the treatment of fungal infections, such as ketoconazole and other azole antifungals.
* Medications for the treatment of depression, such as nefazodone, fluoxetine, fluvoxamine, and sertraline.
* Quinupristin/dalfopristin (a combination antibiotic).
* Cimetidine and cisapride for the treatment of gastrointestinal disorders.
* Valproic acid, a medication for the treatment of epilepsy.
* Quinidine and amiodarone, medications for the treatment of heart rhythm disorders.
* Nifedipine can affect the effectiveness of the following medications:
* Diuretics, beta-blockers, ACE inhibitors, AT1 receptor antagonists, other calcium antagonists, alpha-blockers, and methyldopa, which are blood pressure-lowering agents. The blood pressure-lowering effect can be intensified.
* Medications for the treatment of erectile dysfunction (phosphodiesterase-5 inhibitors), as these medications also lower blood pressure. The blood pressure-lowering effect can be intensified.
* Digoxin, a cardiac tonic. The effectiveness of digoxin can be increased.
* Quinidine, a medication for the treatment of heart rhythm disorders. The effectiveness of quinidine can be reduced.
* Intravenously administered magnesium sulfate, given for the treatment of severe
* Tacrolimus, a medication used to prevent organ transplant rejection. The effectiveness of tacrolimus can be reduced.

**What to be mindful of with food and drink?**Taking grapefruit juice at the same time can enhance the effect of this medicine. When regularly consuming grapefruit juice, this effect can last for at least three days after the last consumption of grapefruit juice. Therefore, do not drink grapefruit juice when using this medicine.

**Pregnancy, breastfeeding, and fertility**Are you pregnant, do you think you might be pregnant, are you planning to become pregnant, or are you breastfeeding? Then contact your doctor or pharmacist before using this medicine.

**Pregnancy**You should not use this medicine during pregnancy unless your medical condition requires it. This may be the case, for example, if you have severely elevated blood pressure that does not respond to standard treatment. Use is particularly discouraged in the first trimester of pregnancy; use in the second or third trimester is only allowed under strict indication from your doctor.

**Breastfeeding**The active substance of this medicine is excreted in breast milk. It is recommended to delay breastfeeding or pumping until 4 hours after taking nifedipine to reduce your child's exposure to nifedipine.

**Fertility**If you are a man and have undergone multiple unsuccessful in vitro fertilization (IVF) attempts for which no explanation can be found, this medicine should be considered as a possible cause.

**Driving and using machinery**This medicine can cause side effects such as dizziness, headache, fatigue, or nausea, which can adversely affect your reaction time. You should take this into account when participating in traffic or operating machinery. This is especially important at the beginning of treatment, after a change in dosage, or when using alcohol concurrently.

**Nifedipine retard contains lactose**This medicine contains lactose. If your doctor has informed you that you are intolerant to certain sugars, please contact your doctor before taking this medicine.

**How to use this medicine?**Always use this medicine exactly as your doctor or pharmacist has instructed you. If you are unsure about the correct usage, please contact your doctor or pharmacist.

**Dosage**The recommended dosage for adults is one tablet of Nifedipine retard 30 mg or 60 mg once a day. The maximum daily dose is 120 mg of nifedipine. This amount corresponds to 4 tablets of Nifedipine retard 30 mg or 2 tablets of Nifedipine retard 60 mg. If your liver is not functioning well, a lower dose may be prescribed.

**Use in children and adolescents under 18 years of age:** This medicine is not recommended for use in children and adolescents under 18 years of age due to limited data on safety and efficacy in this group.

**Duration of treatment:** This medicine is used for a prolonged period.

**Method of administration**You should not chew or break the tablets. It is best to take the tablets in the morning with some liquid (excluding grapefruit juice) at a fixed time. It does not matter whether you take the tablet before, during, or after a meal.

**Have you taken too much of this medicine?**Inform your doctor immediately if you have taken more than the prescribed amount. Taking too much of this medicine can lead to side effects occurring earlier or in a more severe form, especially nausea, vomiting, reduced consciousness to unconsciousness, headache, facial flushing, low blood pressure, elevated blood sugar levels, blood acidification, decreased oxygen levels in the blood, heart rhythm disturbances, and shock associated with congestion of blood in the lung circulation. At very high doses, blood pressure or heart rhythm can drop so significantly that the pulse is no longer detectable. Your doctor may decide to discontinue the treatment with this medicine.

**Have you forgotten to take this medicine?**If you have missed a day, do not take a double dose to make up for a missed tablet. Simply continue with the prescribed dosage.

**If you stop using this medicine**If you abruptly discontinue treatment with this medicine, your blood pressure may increase. Contact your doctor if you wish to terminate the treatment prematurely.

Do you have any other questions about the use of this medicine? Then contact your doctor or pharmacist.

**Possible Side Effects**Like any medicine, this medicine can have side effects, although not everyone gets them.

**Common side effects (occur in less than 1 in 10 users):**

* Fluid retention, including around the ankles
* Headache
* Dilation of blood vessels
* Constipation
* Feeling unwell.

**Uncommon side effects (occur in less than 1 in 100 users):**

* Allergic reaction
* Fluid retention, including in the skin and mucous membranes, e.g., throat/tongue, and in the larynx (edema/angioedema, including laryngeal edema) due to allergic reaction
* Anxiety reactions
* Sleep disturbances
* Dizziness
* Migraine
* Vertigo
* Tremors
* Visual disturbances
* Increased heart rate
* Palpitations
* Low blood pressure
* Blood pressure drop that may be accompanied by fainting
* Nosebleeds
* Stuffy nose
* Abdominal pain
* Nausea
* Upset stomach (dyspepsia)
* Flatulence
* Dry mouth
* Transient increase in certain liver enzymes in the blood
* Red patches on the skin
* Muscle cramps
* Swelling of the joints
* Frequent urination
* Painful and difficult urination
* Erectile dysfunction
* Non-specific pain.
* Chills.
* Rare side effects (occur in less than 1 in 1000 users):
* Itching
* Urticaria (hives)
* Skin rash
* Altered sensation (sensitivity)
* Gum thickening.
* Not known (frequency cannot be estimated from available data):
* Very serious blood disorder (shortage of white blood cells) accompanied by sudden high fever, severe sore throat, and mouth ulcers (agranulocytosis), blood disorder (shortage of white blood cells) associated with increased susceptibility to infections (leukopenia)
* Anaphylactic reaction/shock (severe, life-threatening allergic reaction to certain substances)
* High blood sugar levels (hyperglycemia)
* Decreased sensation (sensitivity)
* Drowsiness
* Eye pain
* Chest pain (angina pectoris)
* Difficulty breathing or other respiratory problems
* Shortness of breath
* Hardening of indigestible tablet shells (bezoar)
* Difficulty swallowing
* Bowel obstruction
* Bowel ulcer
* Vomiting
* Inadequate closure of the junction between the esophagus and the stomach
* Jaundice
* Severe, sudden (hypersensitivity) reaction accompanied by fever and skin blisters/skin peeling (toxic epidermal necrolysis)
* Sunlight sensitivity
* Palpable bruises (palpable purpura)
* Joint pain
* Muscle pain.
* 1 = possibly fatal.

**How to store this medicine?**Keep out of sight and reach of children.

Do not use this medicine after the expiry date which is stated on the packaging after 'EXP'. The last day of that month is the expiry date.

Store in the original packaging to protect from light and moisture. There are no specific storage conditions regarding temperature for this medicine.

Do not dispose of medicines in the sink or toilet or in the household trash. Ask your pharmacist how to dispose of medicines you no longer use. They will be disposed of in an environmentally friendly manner.