User information Please read carefully!

Adalat® retard

Active ingredient: nifedipine **Retard tablets**
Coronary therapeutic/antihypertensive

Composition

1 tablet of Adalat retard contains 20 mg nifedipine.
Other constituents: iron oxide red (E 172), lactose monohydrate, Macrogol 400, magnesium stearate, maize starch, methylhydroxycellulose, microcrystalline cellulose, polysorbate 80, titanium(IV) oxide (E 171).

Indications

1. Treatment of **coronary heart disease** (states with inadequate myocardial oxygen supply):
   - chronic stable angina pectoris (angina of effort)
   - angina pectoris after myocardial infarction (except in the first 8 days following acute myocardial infarction)
2. Treatment of **high blood pressure (hypertension).**

Contraindications

Contraindications are diseases or conditions in which certain drugs must not be administered at all or only after careful assessment by the doctor, as the possible damage in general outweighs the benefits. For the doctor to be in a position to make a careful assessment of any possible contraindications, he must be informed about all previous diseases, concomitant symptoms, and any other concomitant treatment, and your particular circumstances and lifestyle.
Contraindications may occur or emerge only after treatment with this drug has been started. In such cases too the doctor should be informed.
Nifedipine must not be used in cardiovascular shock, more extensive aortic stenosis, or in patients known to be hypersensitive to nifedipine. Care is needed in patients with very low blood pressure (severe hypotension with systolic pressure below 90 mm Hg) or decompensated heart failure.

Use in pregnancy and during breastfeeding

Nifedipine must not be used at any time during pregnancy, as studies in animals have brought to light evidence of embryo damage (malformations). There is no experience in humans.
Nifedipine passes into milk. As there is no experience of possible effects on infants, breastfeeding should be stopped if nifedipine treatment is needed during lactation.

Side effects

In addition to the desired main activity, drugs can also have undesirable effects, so-called side effects. Side effects that have been observed in temporal connection with the use of nifedipine, but which need not necessarily occur in all patients, are mentioned below:
Headaches and flush with a sensation of warmth (erythema, erythromelalgia) may occur, particularly at the beginning of treatment; they are usually transient.
An increase in the heart rate (tachycardia), palpitations and, due to dilation of the blood vessels, lower-leg oedema (collection of fluid in the lower legs) may occasionally occur. There may also be dizziness and tiredness, plus a tingling sensation in the arms and legs (paraesthesia), and a lowering of blood pressure to below the norm (hypotensive circulatory reaction).
Gastrointestinal disturbances such as nausea, feeling of fullness, and diarrhoea occur in rare instances under nifedipine. Skin sensitivity reactions such as pruritus, urticaria, rash (exanthem) are also observed in rare instances, plus isolated cases of exfoliative dermatitis.
Blood picture changes such as anaemia, leucopenia, thrombocytopenia, and thrombocytopenic purpura have been described in connection with taking nifedipine.
Gum alterations (gingival hyperplasia), which regress completely on withdrawal of the drug, may occur in extremely rare cases under longer-term treatment.
Liver function disturbances (intrahepatic cholestasis, increase in transaminases) have been observed in isolated cases, reversible on withdrawal of the therapy.
In rare cases in older men on long-term therapy an enlargement of the mammary glands (gynaecomastia) has been observed, which so far has always regressed completely on withdrawal of the drug.
Elevation of the blood glucose (hyperglycaemia) has been observed in isolated cases. This should be noted particularly when dealing with patients with diabetes mellitus.
Muscle pains (myalgia), trembling of the fingers (tremor), and a slight transient alteration of visual perception have also been observed in isolated cases, especially after high doses.
A (''paradoxical'') increase in anginal pains has been occasionally reported.
In kidney failure there may be a transient deterioration of renal function under nifedipine.
Care should be exercised in dialysis patients with malignant hypertension and a reduction in circulating blood volume (hypovolaemia), since a marked fall in blood pressure may occur as a result of vasodilation.
In the first weeks of treatment there may also be an increase in the volume of urine passed each day.
Patients undergoing antihypertensive therapy with this drug should have regular medical check-ups.
Reactions to the drug – which vary in intensity from one individual to another – can impair the ability to drive or to operate machinery. This applies particularly at the beginning of treatment, on changing medication, and in combination with alcohol.

Interactions with other drugs

The activity of many medicines can be influenced by simultaneous administration of other drugs. You should therefore consult your doctor if you are regularly taking any other drugs, have until recently been taking other drugs, or wish to take other drugs with the present medication. The doctor will then be able to say whether you should expect any drug intolerance under these circumstances, or if any specific measures are required with this medication, such as a change in the dose.

The following interactions between this substance and other drugs should be noted:

The blood-pressure-lowering effect of nifedipine may be potentiated by other antihypertensives and by tricyclic antidepressants. The effects on blood pressure and heart rate are potentiated on combination with nitrates.

When nifedipine is administered simultaneously with β-receptor blockers ("beta-blockers") the patient should be carefully monitored, since fairly severe hypotension may occur; heart failure has also been known to develop occasionally.

Certain drugs from the group of calcium antagonists may potentiate the negative inotropic action of antiarrhythmics such as amiodarone and quinidine. There are no observations for nifedipine on this point.

In isolated cases nifedipine produces a drop in the plasma quinidine level, or there is a clear rise in the plasma quinidine level after withdrawal of nifedipine, so that checks of the plasma quinidine level are recommended in patients on combined therapy.

Nifedipine may produce an increase in the plasma levels of digoxin and theophylline, so that monitoring of their levels is recommended.

Cimetidine and to a smaller extent ranitidine may lead to an increase in the plasma level of nifedipine and thus to increased action of nifedipine.

Dosage guidelines

If possible, the treatment should be adapted to the severity of the disorder and to the responsiveness of the individual patient.

The basic dose should be reached gradually, depending on the particular clinical picture.

Patients with impaired liver function should be monitored carefully; it may be necessary to reduce the dose.

Patients with severe cerebrovascular disease should be treated with a lower dose.

Unless otherwise prescribed, the following dosage guidelines apply:

Adults:	**Basic dose:**
1. For **coronary heart disease**	
– Chronic stable angina (angina of effort)	1 Adalat retard tablet twice a day (20 mg twice daily)
– Angina pectoris after cardiac infarction	1 Adalat retard tablet twice a day (20 mg twice daily)

The basic dose is 2 x 20 mg. This can be increased to 2 x 40 mg/day.

2. For **hypertension**	1 Adalat retard tablet twice a day (20 mg twice daily)

The basic dose is 2 x 20 mg. This can be increased to 2 x 40 mg/day.

Nature and duration of use

Adalat retard is generally swallowed whole with a little liquid after meals.

Taking the drug with food leads to delayed but not reduced absorption.

The interval between the recommended single doses should be not less than 4 h.

Adalat retard should be withdrawn gradually, especially after high doses.

The doctor will determine the duration of use.

Notes

The drug should not be used after the expiry date.

The light-sensitive active ingredient of the retard tablets is protected from light inside and outside its packaging; nevertheless, the tablets should not be removed from the blister foil until just before use.

The retard tablets should not be divided, as otherwise the light protection afforded by the lacquer is no longer guaranteed.

Dosage form and pack size

30 and 100 retard tablets of 20 mg nifedipine

This is a medicament

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.

Keep medicament out of reach of children.

Council of Arab Health Ministers **Union of Arab Pharmacists**

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