



Nifedipine

tablets film-coated, tablets film-coated retard, capsules retard



COMPOSITION :

Nifedipine -5 Capsules
Each capsule contains Nifedipine IP 5 mg.

Nifedipine -10 Capsules
Each capsule contains Nifedipine IP 10 mg.

Nifedipine RETARD Tablets
Each film-coated slow-release tablet contains Nifedipine IP 20 mg.

PHARMACOLOGY :

Pharmacodynamics

Nifedipine is a specific and potent calcium antagonist with mainly vascular effects.

As a specific and potent calcium antagonist, the main action of nifedipine is to relax arterial smooth muscle both in the coronary and peripheral circulation.

In angina pectoris, nifedipine capsules relax peripheral arteries so reducing the load on the left ventricle. Additionally, nifedipine dilates submaximally both clear and pre-stenotic, stenotic and post-stenotic coronary arteries, thus protecting the heart against coronary artery spasm and improving perfusion to the ischaemic myocardium.

Nifedipine reduce the frequency of painful attacks and ischaemic ECG changes, irrespective of the relative contribution from coronary artery spasm or atherosclerosis.

Nifedipine causes a reduction in blood pressure such that the percentage lowering is directly related to its initial level. In normotensive individuals, nifedipine has little or no effect on blood pressure.

Pharmacokinetics :

Nifedipine
Greater than 90% of a single oral or sub-lingual dose of nifedipine is absorbed.

Radioactivity is detected in the serum 20 minutes after an oral dose and 10 minutes after a sub-lingual dose. Maximal equivalent serum concentrations are achieved 1-2 hours after enteral administration and these correspond to the equivalent concentrations over the same time period after intravenous administration (the drug is almost completely absorbed).

After enteral or intravenous doses, 70-80% of activity is eliminated (primarily as metabolites) via the urine. Remaining excretion is via the faeces.

After 24 hours, 90% of the administered dose is eliminated.

Protein binding of nifedipine exceeds 90% in human serum.

Nifedipine RETARD

Absorption and distribution

Nifedipine is absorbed almost completely from the gastro-intestinal tract regardless of the oral formulation used. Protein binding of nifedipine exceeds 90% in human serum.

Metabolism and elimination

Nifedipine undergoes extensive metabolism in the liver to inactive metabolites, with less than 1% of the parent drug appearing unchanged in the urine. The rate of absorption determines the drug's apparent elimination. The apparent elimination phase half-life for Nifedipine RETARD 20 mg tablets has been estimated as 2.2 - 2.4 ± 0.8 hours.





INDICATIONS :

Nifedipine is indicated in the prophylaxis and treatment of vasospastic angina and chronic stable angina, and Raynaud's phenomenon.

Nifedipine RETARD is indicated for the treatment of hypertension. It may be used in combination with other antihypertensive agents. Nifedipine RETARD is also indicated in prophylaxis of chronic stable angina pectoris.

DOSAGE AND ADMINISTRATION :

Nifedipine capsules should be swallowed with a little fluid, during or after food. The dosage should be established by titration. Excessive doses can result in hypotension. Dose range for the treatment of angina is 30 mg to 80 mg/day. The starting dose is 5 mg thrice daily and this is gradually increased over 7 to 14 days as required. For rapid relief in angina, the capsule is bitten and the contents retained in the mouth. Doses more than 180 mg/day is not recommended.

Nifedipine RETARD administered twice daily provides a 24-hour control of raised blood pressure in hypertension as well as a 24-hour control of ischemia in angina pectoris. These tablets should be swallowed whole and should not be bitten or divided.

CONTRAINDICATIONS :

Aortic stenosis, unstable angina, acute angina, acute myocardial infarction, secondary prevention of myocardial infarction and hypersensitivity to the drug or other dihydropyridines

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According to the Indian Trade Mark the company owns about 450 brands and 4600 generic manufacturing permissions in India. According to the export data analysis the company was the largest exporter of generic medicines to the Europe and Middle East countries.

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The company medicines are present in France, Georgia, Egypt and CIF countries.



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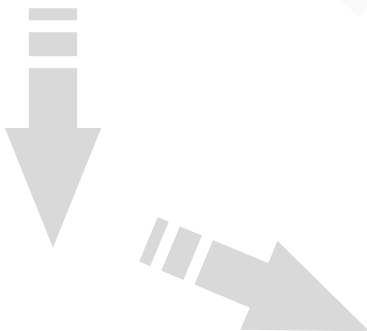
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