

Nictoris®

Nicorandil BP

Description: Nicorandil is a dual-action potassium channel opener that relaxes vascular smooth muscle through membrane hyperpolarization via increased transmembrane potassium conductance and increased intracellular concentration of cyclic GMP. It is shown to dilate normal and stenotic coronary arteries and reduces both ventricular preload and afterload.

Mode of action: Nicorandil provides a dual mode of action leading to relaxation of vascular smooth muscle. A potassium channel opening action provides arterial vasodilation, thus reducing afterload, while the nitrate component promotes venous relaxation and reduction in preload. Nicorandil has a direct effect on coronary arteries without leading to a steal phenomenon. The overall action improves blood flow to post-stenotic regions and the oxygen balance in the myocardium.

Pharmacokinetics: Nicorandil is well absorbed with no significant first-pass metabolism. Maximum plasma concentrations are achieved in 30 to 60 minutes and are directly related to the dosage. Metabolism is mainly by denitration of the molecule into the nicotinamide pathway with less than 20% of an administered dose being excreted in the urine. The main phase of elimination has a half-life of about 1 hour. Nicorandil is only slightly bound to plasma proteins. No clinically relevant modifications in the pharmacokinetic profile have been seen in the elderly or in patients with liver disease or chronic renal failure.

Composition:

Nictoris® 5 mg Tablet: Each tablet contains Nicorandil BP 5 mg.

Nictoris® 10 mg Tablet: Each tablet contains Nicorandil BP 10 mg.

Nictoris® 20 mg Tablet: Each tablet contains Nicorandil BP 20 mg.

Indication:

- ◆ Prevention and long term treatment of chronic stable angina pectoris.
- ◆ Reduction in the risk of acute coronary syndromes in patients with chronic stable angina and at least one of the following risk factors: Previous MI, Previous CABG etc.

Dosage and Administration: The recommended starting dose is 10mg Nicorandil twice daily although up to 30 mg daily may be employed if necessary.

Contraindications: Nicorandil is contraindicated in patients with cardiogenic shock, left ventricular failure with low filling pressures and in hypotension etc.

Side effects: Headache, Dizziness, Nausea, vomiting, cutaneous vasodilation with flushing etc.

Use in pregnancy and Lactation:

Pregnancy: Animal studies have not revealed any harmful effect of Nicorandil on the fetus although there is no experience in humans. It should not be used in pregnant patients unless there is no safer alternative.

Lactation: As it is not known whether Nicorandil is excreted in human milk, breastfeeding should be avoided by lactating mother who require therapy.

Precautions: The use of Nicorandil should be avoided in patients with depleted blood volume, low systolic blood pressure, acute pulmonary edema or acute myocardial infarction with acute left ventricular failure and low filling pressures.

Drug interactions: Nicorandil may interact with anti-hypertensive drugs, vasodilators, tricyclic anti-depressants, PDE-5 inhibitors such as Sildenafil citrate etc.

Over dosage: Acute over dosage is likely to be associated with peripheral vasodilation, decreased blood pressure and reflex tachycardia.

Storage: Keep out of reach of children. Store in a dry place, below 25° C temperature and protected from light.

Packaging:

Nictoris® 5 mg Tablet: Each Carton contains 14x3 tablets in Alu-Alu blister pack.

Nictoris® 10 mg Tablet: Each Carton contains 14x3 tablets in Alu-Alu blister pack.

Nictoris® 20 mg Tablet: Each Carton contains 14x2 tablets in Alu-Alu blister pack.