

Pactorin®

Nitroglycerin

Description: Pactorin® is a preparation of Nitroglycerin. It is a potent coronary vasodilator, which relaxes the muscles of blood vessels, causing an increase in the oxygen supply to the heart. It also reduces venous return, lowers end-diastolic pressure in the right and left ventricles and improves myocardial function. Retard tablets of Nitroglycerin possess sustained effect because its absorption from the gastrointestinal tract is long lasting and continuous, due to the sustained release of active substance from the matrix. Nitroglycerin is suitable for the prevention as well as for reducing the severity of anginal attacks when given in long term treatment. Pactorin® increases the tolerance of anginal patients to exercise and decreases the sublingual Nitroglycerin demand.

Indications: Pactorin® is indicated for the prophylaxis and long term treatment of angina pectoris, adjuvant therapy of congestive heart failure (in combination with digitalis, diuretic, ACE-inhibitor or arterial vasodilator preparation) and myocardial infarction.

Dosage and administration: Pactorin® should be taken before meal. The dosage should be determined individually depending on the severity of the illness and on the patient's condition. **Adult and elderly patients:** The usual starting dose is one tablet 2 times a day in the morning and early afternoon (e.g. at 8 am and 2 pm, with a daily nitrate free interval of 10 to 12 hours), which can be incremented gradually to 2 or 3 tablets 2 times a day. If the attack is primarily nocturnal, then the daily dose should be taken in the morning and bedtime. **Children:** Nitroglycerin is not recommended for use in children. **Use in pregnancy and lactation:** There is no evidence relating to the safety of Nitroglycerin in pregnancy and lactation. Nitroglycerin should not be administered to pregnant women and nursing mothers unless considered essential by the physician.

Precautions: Nitroglycerin should be used cautiously in patients with volume depletion or low systolic blood pressure. Regular use of Nitroglycerin (three times daily) should be avoided because of the developing of tolerance.

Side effects: The common side effect of nitroglycerin is headache (nitrate headache), which is frequent at the beginning of therapy. It is dose dependent and ceases within several days. Rarely, at the time of the first administration, or when the dose is increased blood pressure drops, or orthostatic hypotension may appear with the symptoms of increased heart rate, daze, dizziness and the feeling of weakness. Occasionally, nausea and vomiting may occur.

Contraindications: Nitroglycerin should not be used in patients with history of known hypersensitivity to Nitroglycerin or any of components of this ingredient. It is also contraindicated in patients with increased intracranial pressure, glaucoma.

Drug Interactions: Concomitant use of Nitroglycerin with alcohol may cause hypotension. Patients receiving antihypertensive drugs should be observed for possible additive hypotensive effects.

Overdose: Accidental or deliberate over dosage toxic effects of Nitroglycerin include vomiting, restlessness, cyanosis, methaemoglobinaemia, syncope and tachycardia. Patients should receive gastric aspiration and lavage and be given respiratory and circulatory support.

Pharmaceutical precautions: store in a cool and dry place. Protect from light.

Presentation: Pactorin[®] 2.6 mg tablet: each retard tablet contains nitroglycerin USP 2.6 mg.

Package quantities: Pactorin[®] 2.6 mg tablet: Carton of 50 tablets in blister.

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