

Only for the use of Medical Professionals

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. Nitroglycerin possesses 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 angina attacks when given in long term treatment. Nitroglycerin increases the tolerance of angina patients to exercise. Nitroglycerin applied on the buccal mucosa is absorbed quickly; its effect becomes apparent within 1 minute.

Indications

Pactorin® retard tablet 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.

Pactorin® Spray is indicated for acute relief of an attack or prophylaxis of angina pectoris due to coronary artery disease.

Dosage and administration

Retard Tablet:

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.

Spray:

Adult and elderly patients: At the onset of an attack one or two metered sprays should be administered under the tongue. If necessary, more doses can be given but not more than 3 metered sprays are recommended within a 15 minutes period. If the chest pain persists, prompt medical attention is recommended. **Pactorin®** Spray may be used prophylactically 5 to 10 minutes prior to engaging in activities which might precipitate an acute attack.

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.

Contraindication

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 interaction

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 overdosage 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 precaution

Tablet: Store in a cool and dry place. Protect from light. Keep away from the reach of children.

Spray: Do not puncture, break or incinerate pressurized canister even when apparently empty. Avoid direct sunlight or heat. Store below 25° C. Keep away from eyes. Keep away from children.

Presentation

Pactorin® 2.6 mg Tablet: Each retard tablet contains Nitroglycerin USP 2.6 mg.

Pactorin® Spray: Each actuation delivers Nitroglycerin USP 400 µg.

Package quantities

Pactorin® 2.6 mg Tablet: Carton of 50 tablets in blister.

Pactorin® Spray: Canister of 200 metered actuation.

How to use Pactorin® Spray

1. Sit down if possible as soon as an attack of angina coming on.
2. Remove the plastic cap, do not shake the canister.
3. Hold the canister upright with forefinger on top of the white button.
4. Open the mouth and bring the canister as close to it as possible, aiming it under the tongue.
5. Press the button firmly with the forefinger to release the spray under the tongue.
6. Release the button and close your mouth. Avoid swallowing immediately after administering the spray. The medication should not be expectorated or the mouth rinsed for 5 to 10 minutes following administration.
7. If require a second administration to obtain relief, repeat steps 4, 5 and 6.
8. Replace the plastic cap.

© Registered Trade Mark



**Advanced Chemical
Industries Limited**
7, Hajeegonj Road, Godnol
Narayanganj, Bangladesh

030215/A