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Rx Nitroglycerin Injection IP

Nitroventin™

25mg/5ml

COMPOSITION :
Each ml contains :
Nitroglycerin IP.....5 mg
Water for Injections IP.....q.s.

Pharmacological Properties

Pharmacodynamic properties
Nitroglycerin, an organic nitrate, is a vasodilator. The principal pharmacological action of Nitroglycerin is the relaxation of vascular smooth muscle. Nitroglycerin produces, in a dose-related manner, dilation of both arterial and venous beds. Dilatation of the post-capillary vessels, including large veins, promotes peripheral pooling of blood and decreases venous return to the heart, reducing left ventricular end-diastolic pressure (pre-load).

Arteriolar relaxation reduces systemic vascular resistance and arterial pressure (after-load). Myocardial oxygen consumption or demand (as measured by the pressure-rate product, tension time index and stroke work index) is decreased by both arterial and venous effects of Nitroglycerin, and a more favourable supply demand ratio can be achieved.

Therapeutic doses of intravenous Nitroglycerin reduce systolic, diastolic and mean arterial blood pressure. Effective coronary perfusion pressure is usually maintained, but can be compromised if blood pressure falls excessively or increased heart rate decreases diastolic filling time.

Nitroglycerin reduces elevated central venous and pulmonary capillary wedge pressures, pulmonary vascular resistance and systemic vascular resistance. Heart rate is usually slightly increased, presumably a reflex response to the fall in blood pressure. Cardiac index may be increased, decreased or unchanged.

Patients with elevated left ventricular filling pressure and systemic vascular resistance values in conjunction with a depressed cardiac index are likely to experience an improvement in cardiac index. Alternatively, when filling pressures and cardiac index are normal, cardiac index may be slightly reduced by intravenous Nitroglycerin.

Pharmacokinetic properties
Nitroglycerin is widely distributed in the body with an apparent volume of distribution of 200 L in adult male subjects, and is rapidly metabolised to dinitrates and mononitrates, with a short half-life estimated at 1-4 minutes. This results in a low plasma concentration after intravenous infusion. Nitroglycerin is also well absorbed from the gastro-intestinal tract, but it is not known if it is distributed into milk.

At plasma concentrations of between 50 and 500 mg/ml, the binding of Nitroglycerin to plasma proteins is approximately 60% and 30% respectively. The plasma half-life of Nitroglycerin is about 1-4 minutes.

Incompatibilities
It is recommended that this concentrated and potent drug must be diluted in Dextrose (5%) Injection IP or Sodium Chloride (0.9%) Injection IP prior to its infusion. They also state that no other drug should be admixed with it.

Nitroglycerin is indicated for the prompt control of hypertension during cardiac surgery. It may also be used for the production and maintenance of controlled hypotension during surgical procedures.

Nitroglycerin may be given for the control of myocardial ischaemia and following cardiovascular surgery.

Unresponsive Congestive Cardiac Failure Secondary to Acute Myocardial Infarction: Nitroglycerin may be used in patients presenting with unresponsive congestive heart failure secondary to acute myocardial infarction.

Unstable Angina: Nitroglycerin Injection may be used to reduce myocardial oxygen demand in proportion to the reduction in pre- and after-load. It may be indicated for the control of anginal episodes in patients with unstable angina who do not respond to standard treatment and/or beta-blockers.

It is recommended that blood pressure and pulse rate are regularly monitored during infusion of Nitroglycerin.

Posology and method of administration

Nitroglycerin Injection is a concentrated, potent drug which must be diluted in Dextrose (5%) Injection IP or Sodium Chloride (0.9%) Injection IP prior to its infusion.

The dosage range for most patients is 10-20 mcg/min. However, doses up to 400 mcg/min may be required during surgical procedures.

Contraindications
To those who have or are:
1. Hypersensitive to Nitroglycerin
2. Hypotensive or hypovolaemic
3. Increased intracranial pressure
4. Constrictive periocarditis and pericardial tamponade
5. Severe anaemia and arterial hypoxaemia
6. Taking sildenafil (Viagra)

Dosage: The recommended dose range is 10-200 mcg/min, although larger doses than this have been used. During some surgical procedures, doses of up to 400 mcg/min may be required. In order to maintain the appropriate infusion rate, clinical assessment and regular blood pressure monitoring are necessary. Measurement of pulmonary capillary wedge pressure and cardiac output may also be used to titrate dosage to response.

Precautions
Nitroglycerin Injection should not be administered to patients known to be hypersensitive to organic nitrates, nor should it be given to patients with uncorrected hypovolaemia, severe anaemia or cerebral haemorrhage or hypertension.

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Nitroglycerin should be used with caution in patients presenting with malnutrition, hypothyroidism, severe hypothermia, or severe impairment of hepatic and/or renal function.

Evidence is not available to demonstrate the safety in Nitroglycerin for intracoronary injection.

Nitroglycerin Injection should be used with caution in patients predisposed to closed angle glaucoma.

Interaction with other medicaments and other forms of interaction
Anti-arrhythmics: disopyramide may reduce effect of sublingual nitrates (owing to dry mouth)
Anti-depressants: tricyclics may reduce effects of sublingual nitrates (owing to dry mouth)
Antimuscarinics: antimuscarinics such as atropine and propantheline may reduce effect of sublingual nitrates (owing to dry mouth)
Sildenafil (Viagra): sildenafil has known effects on the nitric oxide / cGMP pathway, and has been shown to potentiate the hypotensive effects of nitrates such as Nitroglycerin Injection.

Special precautions for storage
Store below 30°C. Protect from light.

Open ampoules of Nitroglycerin should be used immediately and any unused portion to be discarded.

Dilutions of Nitroglycerin Injection in Sodium Chloride Injection or Dextrose Injection are stable for 40 hours at room temperature when stored in glass containers or recommended plastic containers. Similar dilutions are stable for 7 days at 2°C-8°C.

Solutions containing 1 mg or 4 mg per Nitroglycerin, diluted in Dextrose 5% Injection IP are stable for up to 72 hours, at room temperature protected from light, using either polycarbonate or polypropylene syringes.

Nitroglycerin is rapidly lost from solutions stored in polyvinylchloride (PVC) containers, and the use of such infusion packs should therefore be avoided.

Nitroglycerin should be administered in the recommended plastic containers (see under **Compatibility**).

Do not use if the solution is discoloured.

Compatibility: Nitroglycerin Injection is compatible with glass infusion bottles and some rigid infusion packs made of polyethylene.

Nitroglycerin Injection may be also be administered using a syringe pump or rigid plastic syringe.

The method of choice of administration should ensure that the drug is given at a constant infusion rate.

Incompatibility: Nitroglycerin Injection is incompatible with polyvinyl chloride (PVC) since 40-80% of the total amount thereof in the final diluted solution for infusion is absorbed by the PVC tubing of the intravenous administration sets.

Surgery: For the control of hypertensive episodes the recommended starting dose is 25 mcg/min increasing in steps to 25 mcg/min at 5 minute intervals until the desired drop in blood pressure is achieved. Although most patients respond to doses between 10-200 mcg/min, doses up to 400 mcg/min have been required during some surgical procedures. In the treatment of preoperative myocardial ischaemia, the recommended starting dose is 15-20 mcg/min increasing in steps of 10-15 mcg/min until the desired effect is achieved.

Unresponsive Congestive Cardiac Failure Secondary to Acute Myocardial Infarction:
The recommended starting dose is 20-25 mcg/min which can be decreased to 10 mcg/min or increased in steps of 20-25 mcg/min at 15-30 minute intervals until the desired effect is achieved.

Unstable angina: The recommended starting dose is 10 mcg/min increasing in steps of 5-10 mcg/min at approximately 30 minute intervals.

Children and the Elderly: The use of Nitroglycerin in children and elderly patients is not recommended, as the safety and effectiveness of Nitroglycerin in children and elderly patients have not been established.

Pregnancy and lactation
The safety of Nitroglycerin during pregnancy and lactation has not been demonstrated and therefore it should not be used in these situations unless considered essential by the physician.

Effects on ability to drive and use machines
Not applicable

Undesirable effects
Adverse reactions to organic nitrates which have been reported include hypotension, tachycardia, nausea, vomiting, diaphoresis, apprehension, headache, restlessness, muscle twitching, retrosternal discomfort, palpitations, dizziness and abdominal pain. Paradoxical bradycardia has rarely been observed.

Overdose
Overdosage usually results in hypotension and tachycardia and can be reversed by elevating the legs or decreasing or terminating the infusion. In severe cases of overdosage, intravenous administration of methoxamine or phenylephrine is recommended.

Presentation
5 Ampoules in carton

Store in a cool and dry place, below 25°C. Protect from light and moisture. Do not allow to freeze.

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