

NITROGLYCERIN INJECTION USP

25mg/5ml

Glyceryl Trinitrate

Composition:

Each ml contains:
Nitroglycerin USP 5 mg
Water for Injection BP q.s.

Therapeutic indications

Glyceryl trinitrate is indicated for:

Refractory congestive heart failure, including that secondary to acute myocardial infarction; acute left-sided heart failure and acute myocardial infarction,
Refractory unstable angina pectoris and coronary insufficiency, including Prinzmetal's angina,
Control of hypertensive episodes and/or myocardial ischemia during and after cardiac surgery,
Induction of controlled hypotension for surgery.

Posology and method of administration

For intravenous use. Glyceryl trinitrate must be administered via a micro-drip infusion pump or similar device that allows for the maintenance of a constant infusion rate.

Recommendations regarding product dilution are presented in this section. For further instructions on product dilution prior to administration, see section 6.6.

Adults

The dose of glyceryl trinitrate must be adjusted to meet the patient's individual needs.

The recommended dosage range is 10 to 200 mcg/min, but up to 400 mcg/min may be required during certain surgical procedures.

Pediatric population

The safety and efficacy of glyceryl trinitrate have not yet been established in children.

Elderly population

There is no evidence that a dosage adjustment is necessary in the elderly.

Use in surgery

An initial dose of 25 mcg/min is recommended for the control of hypertension or to induce hypotension during surgery. This may be increased in increments of 25 mcg/min at 5-minute intervals until blood pressure is stabilized. Doses between 10 and 200 mcg/min are generally sufficient during surgery, although doses of up to 400 mcg/min have been required in some cases.

Myocardial ischemia

Treatment of perioperative myocardial ischemia may be initiated at a dose of 15–20 mcg/min, with subsequent increments of 10–15 mcg/min until the required effect is achieved.

Refractory congestive heart failure:

The recommended initial dose is 20–25 mcg/min. This may be reduced to 10 mcg/min or increased in steps of 20–25 mcg/min every 15 to 30 minutes until the desired effect is achieved.

Unstable angina:

An initial dose of 10 mcg/min is recommended, with increments of 10 mcg/min at intervals of approximately 30 minutes, depending on the patient's needs.

Method of administration

Glyceryl trinitrate may be administered undiluted by slow intravenous infusion using a syringe pump equipped with a glass or rigid plastic syringe.

Alternatively, glyceryl trinitrate may be administered intravenously as a mixture with a suitable vehicle, such as Sodium Chloride Injection BP or Dextrose Injection BP. If diluted, glyceryl trinitrate must be mixed under aseptic conditions immediately after opening.

Prepared mixtures should be administered by intravenous infusion or via a syringe pump to ensure a constant infusion rate.

Close hemodynamic monitoring of the patient is required during glyceryl trinitrate administration.

The dosage of intravenous glyceryl trinitrate must be adjusted to achieve the desired clinical response. Additional dosage adjustments may be necessary—and further monitoring required—for patients with severe hepatic or renal impairment.

Example of mixture preparation

To obtain a glyceryl trinitrate mixture with a concentration of 100 mcg/mL, add 50 mL of glyceryl trinitrate solution (containing 50 mg of glyceryl trinitrate) to 450 mL of infusion vehicle to achieve a final volume of 500 mL.

A dosage of 100 mcg/min can be achieved by administering 60 mL of the mixture per hour.

Glyceryl trinitrate vials are for single use only and must not be treated as multi-dose containers.

Contraindications

● Glyceryl trinitrate must not be used in the following cases:

- Hypersensitivity to the active substance, other nitrates, or any of the excipients listed in Section 6.1.
- Acute circulatory failure (shock, collapse)
- Cardiogenic shock (unless sufficient end-diastolic pressure is maintained by appropriate measures)
- Severe anemia
- Severe cerebral hemorrhage
- Head trauma
- Uncorrected hypovolemia and hypotensive shock
- Hypoxemia and angina caused by hypertrophic obstructive cardiomyopathy
- Constrictive pericarditis
- Pericardial tamponade
- Toxic pulmonary edema
- Phosphodiesterase type 5 (PDE5) inhibitors (e.g., sildenafil, vardenafil, tadalafil) must not be used during nitrate therapy because PDE5 inhibitors can potentiate the vasodilatory effects of glyceryl trinitrate, resulting in severe hypotension
- Conditions associated with increased intracranial pressure
- Myocardial insufficiency due to obstruction, aortic or mitral stenosis, hypertrophic obstructive cardiomyopathy, or constrictive pericarditis

Fertility, pregnancy, and breastfeeding

Fertility

Reproductive toxicity studies conducted in rats and rabbits using various routes of administration revealed no effects on mating, fertility, or general reproductive parameters. No data are available regarding the effect of glyceryl trinitrate on fertility in humans.

Pregnancy

Developmental toxicity studies conducted in rats and rabbits using various routes of administration revealed no effects on embryos, fetuses, or offspring, even at doses toxic to the dam.

Breastfeeding

Available evidence is inconclusive or inadequate to determine the risk to the infant when used during breastfeeding. There is evidence that nitrates are excreted in breast milk and may cause methemoglobinemia in nursing infants. The extent of nitroglycerin excretion in breast milk has not been determined. A risk to the breastfed child cannot be excluded. A decision must be made whether to discontinue breastfeeding or to stop/withhold glyceryl trinitrate therapy, taking into account the benefit of breastfeeding to the child and the benefit of therapy to the woman.

Overdose

Symptoms of overdose

Symptoms may include the following:

Drop in blood pressure \leq 90 mmHg	Pallor
Sweating	Weak pulse
Reflex tachycardia	Collapse
Syncope	Postural dizziness
Headache	Asthenia
Dizziness	Nausea
Vomiting	Diarrhea

Storage

Store protected from light at a temperature between 15°C and 30°C.

Nature and contents of container

Box of 10 ampoules (5 mL)

KEEP MEDICINE OUT OF THE REACH OF CHILDREN

Manufactured in India:

