

GLYCERYL TRINITRATE WOCKHARDT

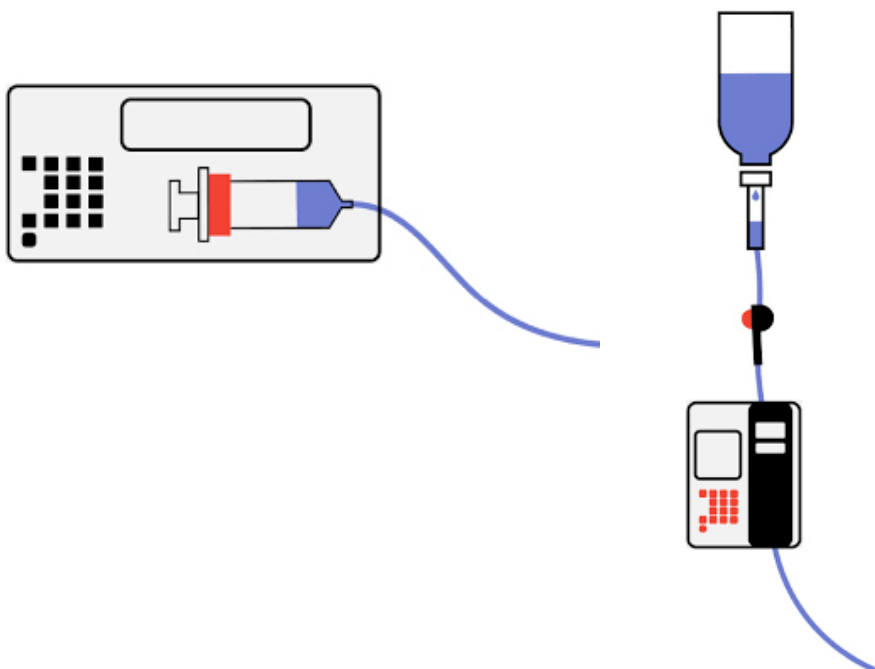
glyceryl trinitrate 50mg/50mL

The only
ready-to-use
GTN Solution
NO DILUTION REQUIRED



50mg in 50mL glass vial

- More convenient dose preparation
- The only TGA approved GTN brand for use without dilution
- The only TGA approved GTN brand for use in concentrations greater than 0.4mg/mL
- Suitable for use with or without dilution in both:
 - Syringe Drivers
 - Infusion Pumps



WOCKHARDT

Distributed in Australia by:
Wockhardt Bio Pty Ltd
c/o InterPharma Pty Ltd
Suite 103 / 39 East Esplanade
Manly NSW 2095
Ph: 02 9976 6876
www.interpharma.com.au

GLYCERYL TRINITRATE WOCKHARDT

glyceryl trinitrate 50mg/50mL

Active Ingredient	Glyceryl trinitrate
Excipients	Glucose, Glucose monohydrate, Propylene glycol
Immediate Container	50mL colourless glass vials
Strength	Each 50mL of GLYCERYL TRINITRATE WOCKHARDT contains 50mg of Glyceryl trinitrate. The solution is preservative free.
Pack Size	Presented in packs of 1 x 50mL glass vial
Stability Unopened	2 years, store below 25°C, protect from light
Stability After 1st Opening	Once the vial has been opened, the product must be used immediately

PLEASE REVIEW FULL PRODUCT INFORMATION BEFORE PRESCRIBING. FULL PRODUCT INFORMATION IS AVAILABLE FROM:

<https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2016-PI-01700-1&d=2016050216114622483>

GLYCERYL TRINITRATE WOCKHARDT (Glyceryl trinitrate 50mg/50mL) CONCENTRATED solution for Injection **Minimum Product Information:** Indications: Blood pressure control in perioperative hypertension; congestive heart failure due to acute myocardial infarction; angina pectoris in patients non-responsive to organic nitrates/beta blocker; controlled hypertension in neurosurgical/orthopaedic surgery procedures. **Contraindications:** Hypersensitivity to glyceryl trinitrate/organic nitrates or excipients; hypotension/uncorrected hypovolemia; increased intracranial pressure; constrictive pericarditis and pericardial tamponade; severe anaemia or arterial hypoxaemia; coadministration of sildenafil and soluble guanylate cyclase stimulator; obstructive cardiomyopathy (especially with aortic or mitral stenosis/constrictive pericarditis). **Precautions:** Glyceryl Trinitrate Wockhardt 50mg/50mL concentrated solution may be administered UNDILUTED by slow intravenous infusion using a syringe driver or small volume infusion pump ONLY. **IF USED AS A DILUTED INFUSION** dilute in 5% glucose OR 0.9% sodium chloride pre-infusion; administration set used affects active amount delivered; only use in acute myocardial infarction for treating definite left ventricular failure; careful dose titration required to avoid precipitous blood pressure decrease; avoid excess hypotension and for prolonged periods; vasodilators use in hypertensive patients suspected of causing acute blindness; tolerance/cross tolerance may occur with long term/repeated use of organic nitrates; nitrate dependence; caution in patients with severe ischaemic heart disease/pulmonary disease due to hypoxaemia; methaemoglobinaemia; patients with malnutrition, hypothermia, hypothyroidism, hyperthyroidism, severe hepatic/renal disease, elderly patients; not recommended in children; contains glucose; may affect certain laboratory tests (refer PI for details). **Interactions:** Alcohol, levodopa, pancuronium, morphine, ergot alkaloids, tricyclic antidepressants, anticholinergics, vasodilators, antihypertensives, major tranquilisers, opioids; aspirin, non-steroidal anti-inflammatory drugs, noradrenaline, sympathomimetics, heparin. **Pregnancy Category B2;** Caution with lactation. **Adverse Events:** Generally dose related; headache, tachycardia, nausea, vomiting, apprehension, restlessness, muscle twitching, retrosternal discomfort, palpitations, dizziness and abdominal pain; hypotension, bradycardia; hyperosmolarity due to propylene glycol solvent. **Dosage:** Product is for single use in one patient only. Discard any residue. Initially 5µg/min (for non-absorbing tubing) then titrated at 5µg/min increments every 3-5 mins according to clinical situation and until response noted. If no response at 20µg/min, use 10µg/min then 20µg/min increments. Once partial response observed, reduce dose increase and lengthen dosage increment interval. No fixed optimum dose; continuous monitoring of physiologic parameters required. **ADMINISTRATION BY SMALL VOLUME INFUSION SYSTEMS** Glyceryl Trinitrate Wockhardt 50mg/50mL concentrated solution may be administered UNDILUTED by slow intravenous infusion using a syringe driver or small volume infusion pump ONLY. Prior to activating the infusion pump, carefully check that the appropriate infusion rate has been set. During glyceryl trinitrate administration there should be close haemodynamic monitoring of the patient. **ADMINISTRATION BY LARGE VOLUME INFUSION** Glyceryl Trinitrate Wockhardt 50mg/50mL concentrated solution may be administered by large volume infusion when DILUTED in 5% glucose or 0.9% sodium chloride prior to its infusion. After the initial dosage titration, the concentration of the admixture solution may be increased, according to clinical response if necessary, to limit fluids given to the patient. If the glyceryl trinitrate concentration is adjusted, it is imperative to flush or replace the infusion set before a new concentration is utilised. Depending on the infusion set used and the flow rate, it could take from 1 to 2 minutes to 3 hours for the new concentration to reach the patients if the infusion set is not flushed or replaced. Due to the problem of glyceryl trinitrate absorption by polyvinyl chloride (PVC) tubing, GLYCERYL TRINITRATE WOCKHARDT should be used with the least absorptive infusion tubing (i.e. non-PVC tubing) available. Administration sets which incorporate polyethylene are recommended. Dosage is affected by the type of containers and administration sets used (see **Section 4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE in Full PI**).

GLYCERYL TRINITRATE WOCKHARDT is supplied as a pack of 1 x 50 mL glass vial.

Refer to full PI for maintenance dilution instructions. Based on Product Information dated 6 Sep 2021. Date of first approval: 7th May 2019



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