Comparative Table: GLYCERYL TRINITRATE INJECTION*

Brand	GLYCERYL TRINITRATE WOCKHARDT	DBL GLYCERYL TRINITRATE, HOSPIRA GLYCERYL TRINITRATE
Container Type and Volume	50mL glass vial	10mL glass ampoule
Content GTN	50mg (1mg per mL)	50mg (5mg per mL)
Preservative Free	Yes	Yes
Route of Administration	i.v.	i.v.
Administration without dilution	Yes	No
Maximum concentration approved for administration	1mg per mL	0.4mg per mL
Ethanol Content	Ethanol free	6.69mL Absolute Ethanol per 10mL (66.9%)
Other Excipients	Glucose	Propylene Glycol
	Glucose monohydrate	Water for Injections
	Propylene Glycol	
	Water for Injections	
Adverse Effects (differences)		Alcohol intoxication has been reported in patients receiving high dose intravenous infusions.

*as per TGA Approved Product Information at the time of publication (September 2021)

WOCKHARDT

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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=20160502161146224 83

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 tranquillisers, 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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