

Glyceryl Trinitrate 1 mg/ml solution for infusion

Read all of this leaflet carefully before you receive this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

The name of your medicine is Glyceryl Trinitrate 1 mg/ml solution for infusion, which will be referred to as Glyceryl Trinitrate throughout this leaflet.

WHAT IS IN THIS LEAFLET:

1. What Glyceryl Trinitrate is and what it is used for
2. What you need to know before you receive Glyceryl Trinitrate
3. How you will be given Glyceryl Trinitrate
4. Possible side effects
5. How to store Glyceryl Trinitrate
6. Contents of the pack and other information

1. WHAT GLYCERYL TRINITRATE IS AND WHAT IT IS USED FOR

Glyceryl Trinitrate belongs to a group of drugs called nitrates. This medicine is used to prevent and relieve the pain or discomfort of an angina attack (chest pain). It relaxes the muscle around blood vessels and makes the heart's work easier.

This solution is only used in hospitals and is given to you by a doctor or nurse. It is used in the following conditions:

- heart failure and acute myocardial infarction (heart attack)
- angina attack
- to lower blood pressure during surgery
- to control blood pressure during and after cardiac surgery

2. WHAT YOU NEED TO KNOW BEFORE YOU RECEIVE GLYCERYL TRINITRATE

You should not be given Glyceryl Trinitrate if:

- you are allergic to glyceryl trinitrate or to any of the other ingredients of this medicine (listed in section 6).
- you are allergic to any other nitrates
- you are taking a medicine for the treatment of erectile dysfunction (e.g. sildenafil (Viagra), vardenafil, tadalafil). If you take Glyceryl Trinitrate concomitantly with such medicines a severe and possibly dangerous fall in blood pressure can occur. This would result in collapse, unconsciousness and could be fatal. You should not take such medicines whilst on Glyceryl Trinitrate treatment.
- you are in shock (a life-threatening medical condition where insufficient blood flow reaches the body tissues)
- you have severe anaemia (lack of red blood cells)
- you have low blood pressure
- you have low blood volume
- you have low blood oxygen (this can make you feel fatigued and short of breath) and angina caused by a heart disease where the muscle mass of the left heart ventricle is enlarged
- you have fluid accumulation in the lung
- you have ever had a serious head injury, cerebral haemorrhage (bleeding in the brain) or a disease which is accompanied by increased pressure on the brain
- you have or had heart conditions
- you are using riociguat, a medicine used in treating pulmonary hypertension.

Warnings and precautions

Talk to your doctor or nurse before being given Glyceryl Trinitrate if:

- you have acute left-sided heart failure - providing that systolic blood pressure (the blood pressure when the heart is contracting) is over 90 mmHg
- you have had an acute myocardial infarction (heart attack) - providing that systolic blood pressure is over 90 mmHg
- you have severe liver or kidney problems
- you have an under active thyroid
- your body temperature is lower than normal (hypothermia)
- you are pregnant or breastfeeding.

Children

This medicine is not recommended in children.

Other medicines and Glyceryl Trinitrate

Tell your doctor or nurse if you are taking, have recently taken or might take any other medicines. This is especially important with the following medicines as they may interact with your Glyceryl Trinitrate:

- **Medicines for the treatment of erectile dysfunction (e.g. Viagra (sildenafil), vardenafil, tadalafil). Use of Glyceryl Trinitrate with these medicines could cause a severe drop in blood pressure and could lead to collapse and unconsciousness, and may be fatal.**
- Medicines which lower blood pressure (e.g. other vasodilators, beta-blockers, calcium channel blockers, ACE inhibitors, monoamine oxidase inhibitors)
- Tricyclic anti-depressants (e.g. amitriptyline, nortriptyline, clomipramine, imipramine)
- Certain very strong pain killers which are similar to morphine (opioids e.g. alfentanil)
- Neuroleptics (medicines used to treat anxiety)
- Sapropterin containing medicines
- Non-steroidal anti-inflammatory drugs (NSAIDs) except acetyl salicylic acid.

Glyceryl Trinitrate with alcohol

Do not drink alcohol whilst using Glyceryl Trinitrate as it can cause your blood pressure to drop. This may make you feel dizzy or faint.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or nurse for advice before being given this medicine.

Driving and using machines

This medicine is used in hospitalised patients. Therefore if you have any concerns ask your doctor or nurse.

3. HOW YOU WILL BE GIVEN GLYCERYL TRINITRATE

Glyceryl Trinitrate will be given to you by your doctor or a nurse and you will be monitored very carefully.

- This solution is always given slowly into the blood stream as a solution for (intravenous) infusion and may be diluted or undiluted.
- The dose depends on the condition. Your doctor will decide the correct dose and duration of therapy for you, while carefully monitoring the effects of the drug.

Use in children

This medicine is not recommended for use in children.

Dosage in adults and the elderly:

- The usual dose is between 10 micrograms and 200 micrograms per minute, but sometimes as much as 400 micrograms per minute may be needed
- The exact dose that the doctor will give you depends on the condition you are being treated for. As a guide:

To control high blood pressure during surgery:

- 25 micrograms per minute will be given as a starting dose
- This may be increased by 25 micrograms per minute at 5 minute intervals until your blood pressure is stabilised
- Doses up to 400 micrograms per minute may occasionally be needed.

To control myocardial ischaemia during and after cardiovascular surgery:

- 15-20 micrograms per minute will be given as a starting dose.
- Depending on your response, the dose may be increased by increments of 10-15 micrograms per minute until the desired effect is obtained.

To treat unstable angina:

- 10 micrograms per minute will be given as a starting dose
- Depending on your response, the dose may be increased or decreased by 10 micrograms every 30 minutes until the desired effect is achieved.

The following information is intended for healthcare professionals only:

PREPARATION GUIDE:

Glyceryl Trinitrate 1 mg/ml solution for infusion

Please refer to the Summary of Product Characteristic for full prescribing and other information.

Therapeutic Indications

- Unresponsive 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 ischaemia during and after cardiac surgery,
- Induction of controlled hypotension for surgery.

Administration

For intravenous use.

Glyceryl Trinitrate need not be diluted before use but can be diluted by 1:10 up to 1:40 with 5 % glucose solution, 5 % glucose solution and 0.9 % sodium chloride solution, or with 0.9 % sodium chloride solution.

The solution, whether or not diluted, should be infused slowly and not given by bolus injection.

To ensure a constant infusion rate of glyceryl trinitrate it is recommended that Glyceryl Trinitrate be administered by means of a syringe pump or polyethylene infusion bag with a counter, or with a glass or rigid polyethylene syringe and polyethylene tubing. Systems made of polyvinyl chloride (PVC) may absorb up to 50% of the glyceryl trinitrate from the solution. During Glyceryl Trinitrate administration there should be close haemodynamic monitoring of the patient.

Example of admixture preparation

To obtain an admixture of Glyceryl Trinitrate at a concentration of 100 micrograms/ml, add 50 ml Glyceryl Trinitrate solution (containing 50 mg glyceryl trinitrate) to 450 ml of infusion vehicle to give a final volume of 500 ml.

A dosage of 100 micrograms/min. can be obtained by giving 60 ml of the admixture per hour.

Vials of Glyceryl Trinitrate are for single use only and should not be regarded as multi-dose containers.

Treat heart failure following a heart attack:

- 20-25 micrograms per minute will be given as a starting dose
- Depending on your needs, the doctor may decrease the dose by 10 micrograms per minute or give you a further 20-25 micrograms per minute until the required effect is obtained.

While you are being given Glyceryl Trinitrate, the doctor may monitor your heart rate and breathing to make sure that the medicine is working properly.

If you receive more Glyceryl Trinitrate than you should

Since Glyceryl Trinitrate will be administered to you by a doctor or nurse, it is unlikely that you will be given too much. In the event of overdose following signs or symptoms can occur vomiting, restlessness, fall in blood pressure, coldness of the skin, breathing difficulties, mental illness, blue discolouration of the skin, slow heart rate of less than 60 beats per minute, a temporary loss of consciousness and posture and a very rare blood disorder where the blood is unable to carry oxygen to cells in the body.

These symptoms may be readily reversed by discontinuing your treatment, therefore please tell your doctor or nurse immediately if one or more of these symptoms occur.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Glyceryl Trinitrate can cause side effects, although not everybody gets them. These side effects require special management to minimise the risk of complications. Your doctor will discuss these side effects with you and explain the risks and benefits of your treatment.

Tell your doctor **immediately** if you experience the following:

- An allergic skin reaction – this occurs uncommonly. Symptoms may include skin rash, redness, itch, burning sensation, irritation.

The following side effects have been reported:

Very common (may affect more than 1 in 10 people):

- headache

Common (may affect up to 1 in 10 people):

- sleepiness
- low blood pressure (hypotension) and light-headedness upon standing which you may experience as dizziness, drowsiness, rapid heartbeat (reflex tachycardia) and a feeling of weakness at the start of treatment or when the dosage is increased.

Uncommon (may affect up to 1 in 100 people):

- feeling sick (nausea)
- being sick (vomiting)
- collapse sometimes with a slow heartbeat and fainting
- very low blood pressure (severe hypotension) where you may be sick, feel sick, feel restless, have pale skin and sweat a great deal. This may lead to a worsening of the chest pain you often get with angina
- temporary low oxygen level in the blood (temporary hypoxaemia). For people with heart disease this may lead to low oxygen level in the tissue surrounding the heart (myocardial hypoxia)
- Allergic skin rash, which may be severe

Very rare (may affect up to 1 in 10,000 people):

- Heartburn

Not known (frequency cannot be estimated from the available data)

- irregular heart beat (palpitations)
- flushing
- low blood pressure
- very red skin with scaling and thickened itchy skin (exfoliative dermatitis)
- heart rate increase
- rash

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE GLYCERYL TRINITRATE

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label and carton after "Exp". The expiry date refers to the last day of that month.

Glyceryl Trinitrate ampoules and vials will be stored below 25°C in the outer carton to protect the medicine from light.

Posology

The posology of Glyceryl Trinitrate should be adjusted to achieve the desired clinical response.

Use in surgery

A starting dose of 25 micrograms/min is recommended for the control of hypertension, or to produce hypotension during surgery. This may be increased by increments of 25 micrograms/min at 5 minute intervals until the blood pressure is stabilised. Doses between 10 - 200 micrograms/min are usually sufficient during surgery, although doses of up to 400 micrograms/min have been required in some cases.

Myocardial ischaemia

The treatment of perioperative myocardial ischaemia may be started with a dose of 15 - 20 micrograms/min, with subsequent increments of 10 - 15 micrograms/min until the required effect is obtained.

Unresponsive congestive heart failure

The recommended starting dose is 20 - 25 micrograms/min. This may be decreased to 10 micrograms/min, or increased in steps of 20-25 micrograms/min every 15 – 30 minutes until the desired effect is obtained.

Unstable angina

An initial dose of 10 micrograms/min is recommended with increments of 10 micrograms/min being made at approximately 30 minute intervals according to the needs of the patient

This medicine should not be given to you if the solution for infusion shows any discolouration, precipitation or any other visible particles.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Glyceryl Trinitrate contains:

- The **active substance** is glyceryl trinitrate.
1 ml solution for infusion contains 1 mg glyceryl trinitrate.
- The **other ingredients** are water for injections, glucose monohydrate and hydrochloric acid.

What Glyceryl Trinitrate looks like and the contents of the pack

The product is a clear and colourless solution for infusion. This solution is packed in boxes containing:

- 10 ampoules with 5 ml
- 10 ampoules with 10 ml
- 10 ampoules with 25 ml
- 1 vial with 50 ml
- 10 vials with 50 ml
- 25 vials with 50 ml

Vials are closed with bromobutyl rubber stoppers.

Not all pack sizes may be marketed.

Marketing Authorisation Holder:

hameln pharma ltd,
Gloucester, GL3 4AG, United Kingdom

Manufacturer:

Siegfried Hameln GmbH,
Langes Feld 13, 31789 Hameln, Germany

This package leaflet was last revised in April 2021.

44480/15/21

