

Package leaflet: Information for the user

Glyceryl Trinitrate 5 mg/ml Sterile Concentrate glyceryl trinitrate

Read all of this leaflet carefully before you start using 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, pharmacist or nurse.
- 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.

What is in this leaflet

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

1. What Glyceryl Trinitrate Sterile Concentrate is and what it is used for

Glyceryl Trinitrate Sterile Concentrate is a vasodilator (a medicine that widens the blood vessels).

Glyceryl trinitrate is used for the control of blood pressure during operations or to improve blood flow during and after heart operations. It can also be given to you after you have had a heart attack or to control angina attacks (sudden pains in the chest) when other medicines have not worked.

2. What you need to know before Glyceryl Trinitrate Sterile Concentrate is used

Glyceryl Trinitrate Sterile Concentrate should not be used

- if you are allergic to glyceryl trinitrate or medicines of the same group (organic nitrates) or to any of the other ingredients of this medicine (listed in section 6)
- if you have low blood pressure or a low blood volume (e.g. if you have had severe blood loss)
- if you suffer from increased intracranial pressure (high pressure within the skull)
- if you have had a 'bleed' on the brain
- if you have inflammation of the outer lining of the heart or compression of the heart due to the collection of fluid around the heart
- if you are very anaemic (low iron content or low levels of blood cells in your blood)
- if you have low oxygen levels in your blood
- if you are taking sildenafil (Viagra) or similar medicines used for the treatment of erection problems in men or high blood pressure in the arteries of the lungs that can lead to heart failure (pulmonary arterial hypertension)
- if you have angina pectoris (pain or uncomfortable feeling in the chest) that is caused by a specific heart disease called hypertrophic obstructive cardiomyopathy (insufficient heart blood flow due to obstruction).

- if you are taking a guanylate cyclase stimulator e.g. riociguat due to the likelihood to increase lowering of blood pressure

If possible, tell your doctor if you think any of the above applies to you before this medicine is used.

Warnings and precautions

Special care needs to be taken with Glyceryl Trinitrate Sterile Concentrate

- if you are undernourished
- if your thyroid is not working properly
- if you have a low body temperature
- if you have severe liver or kidney problems
- if you have an eye condition called ‘closed angle glaucoma’ or you have a higher than normal risk of getting it

Severe low blood pressure (hypotension) may occur with even small doses of Glyceryl Trinitrate.

If possible, tell your doctor if you think any of the above applies to you before this medicine is used.

Children

The use of this medicine is not recommended in children.

Other medicines and Glyceryl Trinitrate Sterile Concentrate

Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

Special care is needed if you are taking/using other medicines as some could interact with glyceryl trinitrate. For example:

- it is important that glyceryl trinitrate and sildenafil (a medicine taken to correct erectile dysfunction in men) are not used together because they can cause blood pressure to fall too low
- medicines used to treat high blood pressure
- tricyclic anti-depressants, medicines used to treat depression
- morphine-like painkillers
- it is important that glyceryl trinitrate and medicines known as guanylate cyclase stimulators such as riociguat are not taken together due to the likelihood that your blood pressure would fall too low
- heparin, a blood thinner used to prevent blood clots.

Pregnancy, breast-feeding and fertility

If you are pregnant, or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor, pharmacist or nurse for advice before taking this medicine. Your doctor will only use this medicine if the expected benefits outweigh any potential risk to your baby.

Pregnancy

Glyceryl Trinitrate Sterile Concentrate contains propylene glycol and alcohol (ethanol). If you are pregnant you should talk to your doctor or pharmacist before taking this medicine (see "Glyceryl Trinitrate Sterile Concentrate contains alcohol (ethanol) and propylene glycol").

Breast-feeding

Glyceryl Trinitrate Sterile Concentrate contains propylene glycol and alcohol (ethanol), which may pass into breast milk. If you are breast-feeding, do not take this medicine unless recommended by your doctor (see Glyceryl Trinitrate Sterile Concentrate contains alcohol (ethanol) and propylene glycol ").

Driving and using machines

Do not drive or use machines if you experience any side effect (e.g. dizziness) which may lessen your ability to do so. (see also section 4 **Possible side effects**)

Glyceryl Trinitrate Sterile Concentrate contains an amount of alcohol (ethanol) that can affect your ability to drive or use machines. This is because it may affect your judgement and how fast you react.

Glyceryl Trinitrate Sterile Concentrate contains alcohol (ethanol) and propylene glycol

This medicine contains 2639.2 mg alcohol (ethanol) in each 5 ml ampoule and 5278.4 mg alcohol (ethanol) in each 10 ml ampoule which is equivalent to 527.84 mg/ml (52.78% w/v). The amount of alcohol in each 5 ml ampoule of Glyceryl Trinitrate Sterile Concentrate is equivalent to less than 66 ml of beer or 27 ml of wine. The amount of alcohol in each 10 ml ampoule of Glyceryl Trinitrate Sterile Concentrate is equivalent to less than 132 ml of beer or 53 ml of wine.

The amount of alcohol in this medicine is likely to affect babies and children. These effects may include feeling sleepy and changes in behaviour. It may also affect their ability to concentrate and take part in physical activities.

If you have epilepsy or liver problems, talk to your doctor or pharmacist before taking this medicine.

If you are addicted to alcohol, talk to your doctor or pharmacist before taking this medicine. The amount of alcohol in this medicine may alter the effects of other medicines. Talk to your doctor or pharmacist if you are taking other medicines.

This medicine contains 223.6 mg propylene glycol in each 5 ml ampoule and 447.2 mg propylene glycol in each 10 ml ampoule which is equivalent to 44.72 mg/ml.

If your child is less than 5 years old, talk to your doctor or pharmacist before giving them this medicine, in particular if they are being given other medicines that contain propylene glycol or alcohol.

Propylene glycol can lead to hyperosmolality, haemolysis (destruction of red blood cells which leads to the release of hemoglobin into the blood plasma) and lactic acidosis (lactic acid build up in the bloodstream).

If you are pregnant or breast-feeding, or if you suffer from liver or kidney disease, do not take this medicine unless recommended by your doctor. Your doctor may carry out extra checks while you are taking this medicine.

3. How Glyceryl Trinitrate Sterile Concentrate is used

The medicine will be diluted in a suitable infusion solution and given as an infusion (drip) into a vein. It must not be given by a bolus injection.

Dose

Your doctor will work out the correct dose of glyceryl trinitrate for you and how often it must be given.

The dose of medicine given to you will depend upon your medical condition. An initial dose will be given and depending on how your body reacts, this may be gradually increased.

The infusion rate is typically between 10 and 200 microgram/min.

Treatment should not last more than three days.

Your blood pressure and pulse may be measured often whilst you are being given this medicine.

Use in children

The safety and effectiveness has not been established in this age group therefore the use of glyceryl trinitrate is not recommended in children.

Use in elderly

There is no evidence that a change in dose is required in the elderly.

If you are given too much or too little Glyceryl Trinitrate Sterile Concentrate

This medicine will be given to you in a hospital, under the supervision of a doctor. It is unlikely that you will be given too much or too little, however, tell your doctor or nurse if you have any concerns.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Very common side effects:

- headache

Common side effects:

- abnormally fast, slow or irregular heartbeat
- low blood pressure (you may feel dizzy or faint, particularly when standing up suddenly or getting out of bed)
- sleepiness or feeling drowsy
- weakness

Uncommon side effects:

- chest pain
- heart failure
- feeling sick
- vomiting
- allergic skin reactions (skin rash, redness, itch, burning sensation, irritation)

Very rare:

- heartburn

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 Sterile Concentrate

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

Expiry

This medicine must not be used after the expiry date which is stated on the ampoule label and carton after 'EXP'. Where only a month and year is stated, the expiry date refers to the last day of that month.

Storage

Do not store above 25°C. Keep the ampoules in the outer carton in order to protect from light.

Prepared infusions should be used immediately, however, if this is not possible they can be stored for up to 24 hours in a refrigerator. Storage for longer periods may be possible provided the infusion has been prepared in a way to exclude microbial contamination.

Visible signs of deterioration

Glyceryl Trinitrate Sterile Concentrate and the prepared infusion should be clear and practically colourless. Discoloured solutions should not be used.

6. Contents of the pack and other information

What Glyceryl Trinitrate Sterile Concentrate contains

The active substance is glyceryl trinitrate. Each millilitre (ml) of solution contains 5 milligrams (mg) of glyceryl trinitrate.

The other ingredients are ethanol, propylene glycol (E1520) and water for injections (see section 2 “Glyceryl Trinitrate Sterile Concentrate contains alcohol (ethanol) and propylene glycol”).

What Glyceryl Trinitrate Sterile Concentrate looks like and contents of the pack

Glyceryl Trinitrate Sterile Concentrate is a clear, practically colourless concentrate for solution for infusion which comes in glass containers called ampoules.

It may be supplied in packs containing:

- 5 x 25 mg/5 ml ampoules
- 5 x 50 mg/10 ml ampoules

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Hospira UK Limited
Walton Oaks
Walton-On-The-Hill
Dorking Road
Tadworth
Surrey
KT20 7NS
UK

Manufacturer

Siegfried Hameln GmbH

Langes Feld 13

31789 Hameln

Germany

This leaflet was last revised in 03/2024.

Ref gxGY 6_0

Glyceryl Trinitrate 5 mg/ml Sterile Concentrate

The following information is intended for medical or healthcare professionals only

Further to the information included in section 3, practical information on the preparation/handling of the medicinal product is provided here.

Incompatibilities

Glyceryl Trinitrate Sterile Concentrate is incompatible with polyvinylchloride (PVC) and severe losses of glyceryl trinitrate (over 40%) may occur if this material is used. Contact with polyvinylchloride bags should be avoided. Polyurethane also induces a loss of the active ingredient.

No other drug should be admixed with this medicinal product.

Instructions for use and handling

Not to be given by bolus injection.

Glyceryl Trinitrate Sterile Concentrate is a concentrated, potent drug which must be diluted in Dextrose (5%) Injection BP or Sodium Chloride (0.9%) Injection BP prior to its infusion.

Glyceryl Trinitrate Sterile Concentrate must be mixed under aseptic conditions immediately after opening.

Admixtures are prepared by replacing a given volume of infusion vehicle with an equal volume of the product to produce the final infusion solution.

Example of admixture preparation.

To obtain an admixture of glyceryl trinitrate at a concentration of 100 micrograms/ml add 10 ml (containing 50 mg glyceryl trinitrate) to 490 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 this admixture per hour. This is equivalent to a drip rate of 20 standard drops per minute or 60 paediatric microdrops per minute. At this drip rate the mixture provides enough solution for an infusion time of 8 hours 20 minutes.

Compatible with commonly employed infusion solutions, Sodium Chloride (0.9%) Injection and Dextrose (5%) Injection.

Compatible with glass infusion bottles and rigid infusion packs made of polyethylene.

Open ampoules of glyceryl trinitrate should be used immediately and any unused portion discarded.

Do not use if the solution is discoloured.

In use storage precautions

Following dilution in either 0.9% sodium chloride or 5% dextrose injection solutions in glass containers, chemical and physical in-use stability has been demonstrated for 7 days at both 18°C and 4°C.

Following dilution in 5% dextrose solution in polycarbonate or polypropylene syringes at concentrations of 1 mg or 4 mg per ml protected from light, chemical and physical in-use stability has been demonstrated for 72 hours at room temperature.

However, from a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2-8°C, unless dilution has taken place in controlled and validated aseptic conditions.