

Package Leaflet: Information for the user

Glyceryl Trinitrate 5mg/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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Glyceryl Trinitrate 5mg/ml Sterile Concentrate is and what it is used for
2. What you need to know before you use Glyceryl Trinitrate 5mg/ml Sterile Concentrate
3. How to use Glyceryl Trinitrate 5mg/ml Sterile Concentrate
4. Possible side effects
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1. What Glyceryl Trinitrate 5mg/ml Sterile Concentrate is and what it is used for

Glyceryl Trinitrate 5mg/ml Sterile Concentrate contains glyceryl trinitrate which 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.

You must talk to a doctor if you do not feel better or if you feel worse.

2. What you need to know before you use Glyceryl Trinitrate 5mg/ml Sterile Concentrate

Do not use Glyceryl Trinitrate 5mg/ml Sterile Concentrate:

- if you are allergic to glyceryl trinitrate or medicines of the same group (organic nitrates) or any of the other ingredients of this medicine (listed in section 6)
- if you have low blood pressure or a low volume of blood in your circulation (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 have low oxygen levels in your blood
- if you have severe anaemia (low levels of red blood cells in your blood)
- if you are taking a medicine called sildenafil (a medicine taken to correct erectile dysfunction in men) or similar medicines (phosphodiesterase inhibitors) used for the treatment of erectile problems in men or high blood pressure in the arteries of the lungs
- if you have a specific heart disease called hypertrophic obstructive cardiomyopathy causing your angina (chest pain)

- if you are taking a guanylate cyclase stimulator such as riociguat

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

Warnings and precautions

Talk to your doctor or pharmacist or nurse before using Glyceryl Trinitrate 5mg/ml 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.

Children

The use of this medicine is not recommended in children.

Other medicines and Glyceryl Trinitrate 5mg/ml Sterile Concentrate

Tell your doctor, pharmacist or nurse if you are using, have recently used or might use any other medicines, for example:

- it is important that glyceryl trinitrate and drugs known as phosphodiesterase inhibitors such as sildenafil (a medicine taken to correct erectile dysfunction in men) are not used together because they can cause blood pressure to fall too low.
- 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
- medicines to treat high blood pressure and heart conditions (e.g. diuretics and ACE inhibitors)
- medicines which reduce blood pressure (e.g. beta-blockers, calcium channel blockers and vasodilators)
- tricyclic anti-depressants, medicines used to treat depression
- neuroleptics (used to treat anxiety)
- morphine-like painkillers
- ergot alkaloids used to treat migraines
- aspirin
- heparin, a blood thinner used to prevent blood clots.

Glyceryl Trinitrate 5mg/ml Sterile Concentrate with food, drink and alcohol

Do not drink alcohol whilst using Glyceryl Trinitrate 5mg/ml Sterile Concentrate as it can cause your blood pressure to drop. This may make you may feel dizzy or faint.

Pregnancy, breast-feeding and fertility

Tell your doctor if you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

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 ").

Your doctor will only use this medicine if the expected benefits outweigh any potential risk to the baby.

Driving and using machines

You should not drive or use machines if you experience any side effects (e.g. dizziness, weakness or fast heart rate) which may lessen your ability to do so. (see also section 4 - Possible side effects).

Glyceryl Trinitrate 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 5mg/ml 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 to use Glyceryl Trinitrate 5mg/ml Sterile Concentrate

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.

Recommended 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 micrograms/min. During surgery doses up to 400 micrograms/min may be used. 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 the 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 have side effects, although not everybody gets them.

If any of the following happen, tell your doctor immediately:

- severe allergic reaction – you may experience a sudden itchy rash (hives), swelling of the hands, feet, ankles, face, lips, mouth or throat (which may cause difficulty in swallowing or breathing), and you may feel you are going to faint.

These are very serious side effects. You may need urgent medical attention.

If you experience any of the following tell your doctor as soon as possible:

- low blood pressure (you may feel dizzy or faint, particularly when standing up or getting out of bed)
- flushing
- abnormal or fast heart beats (palpitations)
- slow heart beats
- feeling sick or retching

- excessive sweating
- anxiety
- headache
- restlessness
- muscle twitching
- pain behind the breast bone
- dizziness
- fainting
- pain in your abdomen

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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Ireland

HPRA Pharmacovigilance

Website: www.hpra.ie

Cyprus

Pharmaceutical Services

Ministry of Health

CY-1475 Nicosia

Tel.: +357 22608607

Fax: + 357 22608669

Website: www.moh.gov.cy/phs

5. How to store Glyceryl Trinitrate 5mg/ml Sterile Concentrate

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

Expiry

Do not use this medicine after the expiry date which is stated on the ampoule and carton after 'EXP'. Where only a month and year is stated, the expiry date refers to the last day of that month.

Storage conditions

The ampoules should not be stored above 25°C. The ampoules should be kept in the outer carton in order to protect from light.

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

Prepared infusions: as this product will be given to you in hospital please ask your doctor, nurse or pharmacist if you have any questions.

Visible signs of deterioration

Glyceryl Trinitrate 5mg/ml Sterile Concentrate and the prepared infusion should be clear and practically colourless. This medicine should not be used if the solution is discoloured.

Medicines should not be disposed of 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 5mg/ml 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 5 mg/ml Sterile Concentrate contains alcohol (ethanol) and propylene glycol”.

What Glyceryl Trinitrate 5mg/ml Sterile Concentrate looks like and contents of the pack

Glyceryl Trinitrate 5mg/ml 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:

Ireland:

Pfizer Healthcare Ireland Unlimited Company
The Watermarque Building
Ringsend Road,
Dublin 4,
D04 K7N3,
Ireland

Cyprus:

Pfizer Hellas A.E.
243 Messoghion Ave.
Neo Psychiko 15451

Greece

Local Representative for Cyprus:

Pfizer Hellas A.E. (Cyprus Branch)
Tel.: +357 22817690

Manufacturer:

Pfizer Service Company BV
Hoge Wei 10
1930 Zaventem
Belgium

Siegfried Hameln GmbH
Langes Feld 13
31789 Hameln

Germany

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The following information is intended for medical or healthcare professionals only.

Glyceryl Trinitrate 5 mg/ml Sterile Concentrate

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

Incompatibilities

Glyceryl Trinitrate 5mg/ml 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 5mg/ml 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.

Example of admixture preparation

To obtain an admixture of GTN at a concentration of 100 microgram/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 microgram/min can be obtained by giving 60 ml of the admixture per hour. This is equivalent to a drip rate of 20 standard drops per minute or 60 micro drops per minute. At this drop 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.

Storage

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

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

In-use: Following dilution in either 0.9% sodium chloride or 5% dextrose 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.