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

Glyceryl Trinitrate Sterile Concentrate is a vasodilator (a medication that widens the blood vessels). Glyceryl Trinitrate Sterile Concentrate is used for the control of pressure in vessel/infusion lines, to improve blood flow during and after heart operations. It can also be given to you after you have had a heart attack in order to control an adverse effect (sudden pain in the chest) when other medicines have not worked.

Before Glyceryl Trinitrate Sterile Concentrate is used

Glyceryl Trinitrate Sterile Concentrate should not be used

- if you have shown signs of hypersensitivity (severe allergy) to glyceryl trinitrate or medicines of the same drug group related to it
- if you have low blood pressure or a low blood volume (e.g. if you have had severe losses)
- if you suffer from increased intracranial pressure (high pressure within the skull)
- if you have had a brain tumor on the brain
- if you have hemorrhage of the outer lining of the heart or compression of the heart due to a mass
- if you are taking disopyramide or in case of medicines used for the treatment of arrhythmia 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 engorge vessels (cyanosis or uncompublicable feeling in the chest) that is caused to a specific heart disease called hypertrophic obstructive cardiomyopathy (significant)
- if you are taking a quinapril (a diuretic) even for oral use because this could cause kidney problems
- if possible, tell your doctor if you think any of the above applies to you before you take this medicine

Special care needs to be taken with Glyceryl Trinitrate Sterile Concentrate

- if you are underweight
- if your heart is not working properly
- if you are taking medicines which lower your blood pressure too fast
- if you have severe liver or kidney problems
- if you have a history condition called ‘classic angle glaucoma’ or you have a higher than normal risk of getting it
- if possible, tell your doctor if you think any of the above applies to you before you take this medicine

The use of this medicine is not recommended in children.

Taking/using other medicines

Glyceryl Trinitrate Sterile Concentrate can be taken together with other medicines as some could interact with glyceryl trinitrate. For example:
- in the rare event of taking one or more medicines and which are drugs used to treat diabetes (insulin dysfunction in men) are not used together because they can cause blood pressure to fall too low
- medicines used to treat high blood pressure
- Anticoagulants, medicines used to treat depression
- Anticoagulants, medicines used to treat depression
- Morphine-like painkillers
- Medicines that are used to treat arrhythmia and medicines known as quinapril which is used to treat arrhythmia
- It is not safe to use this medicine together because the blood pressure would fall too low
- Please tell or remind your doctor if you are taking medicines which you have recently taken any other medicines, including medicines obtained without a prescription

Pregnancy and breastfeeding

Tell your doctor if you are pregnant, trying to become pregnant or breastfeeding. Your doctor or pharmacist may advise you to stop using this medicine if it is expected benefits outweigh any potential risks to your baby.

To obtain advice from your pharmacist if you are trying to become pregnant or breastfeeding, your doctor or pharmacist may advise you to stop using this medicine if it is expected benefits outweigh any potential risks to your baby.

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 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/administration of this medicinal product is provided here.

Incompatibilities

Glyceryl Trinitrate Sterile Concentrate is incompatible with polyethylene glycol (PEG) and sodium chloride. Glyceryl trinitrate Sterile Concentrate is also incompatible with solutions of sodium chloride, but it can be used in solutions containing sodium bicarbonate, provided that medicines are given only together with alkali or neutralizing ingredients.

No other drug should be admixed with this medicinal product.

Instructions for use and handling

Glyceryl Trinitrate Sterile Concentrate should be used with extreme care

- for administration to patients by a hospital pharmacist

- Asthma sufferers are prescribed to replace a given volume of infusion vehicle with an equal volume of the product to produce the final infusion

- Example of admixture preparation.

To obtain a volume of glyceryl trinitrate at a concentration of 100 micrograms/ml add 10 ml (containing 90 mg glyceryl trinitrate) to 400 ml of infusion vehicle to give a final volume of 350 ml.
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 and Water for Injections. See section 2 for further information regarding ethanol.

Glyceryl Trinitrate Sterile Concentrate looks like and contents of the pack

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

It may be supplied in packs containing:

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

Not all packs may be marketed.

Marketing authorisation holder and manufacturer

Hospic UK Limited
Horton, Horton Lane
Cambridge CB5 8QF
UK

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A dose of 100 microgram/min can be given by giving 60 ml of this admixture per hour. This is equivalent to a drip rate of 20 standard drops per minute or 60 drop accurately at a flow rate of 5 ml/min. At this drip rate the mixture provides enough solution for an infusion time of 6 hours in adults.

Compatibility 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 containers of Glyceryl Trinitrate Sterile Concentrate should be used immediately and any unused portion discarded.

Do not use the solution is discontinued.

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 5°C.

Following dilution in 5% dextrose solution in polyvinylchloride or polyethylene syringes at concentrations of 10 microgram/ml (or 4 micrograms/ml) or 100 microgram/ml (20 micrograms/ml) or 500 microgram/ml (100 micrograms/ml) or 1000 microgram/ml (200 micrograms/ml) from light, chemical and physical in-use stability has been demonstrated for 72 hours at room temperature.

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

Not all packs may be marketed.

• heartburn
• chest pain
• dizziness

Common side effects:

Like all medicines, glyceryl trinitrate can cause side effects, although not everybody gets them.

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects this leaflet does not mention. You can also report side effects directly via the Yellow Card scheme. By reporting side effects you can help provide more information on the safety of this medicine.

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

Storage

The ampoules should be kept in the outer carton, in order to protect from light, and stored at:

- 2°C to 8°C

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.

Warning

Signs of irritation

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

The product will be given in a suitable infusion solution and given as an infusion (drip) into a vein. It must not be given by a subcutaneous route.

Dose

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

The dose of medication 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.

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 get too much or too little, however, tell your doctor or nurse if you have any concern.

4. POSSIBLE SIDE EFFECTS

Leaves such as inorganic nitrites can cause side effects, although not everybody gets them.

Common side effects:

- you may have headaches, abnormally fast, slow, or irregular heartbeat, feel dizzy when standing up suddenly, weakness and feel sick whilst being given Glyceryl Trinitrate Sterile Concentrate
- you may feel very sleepy
- you may feel nervous
- you may feel hot
- you may feel hungry
- you may feel light-headed
- you may feel light-headed

Other side effects:

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects this leaflet does not mention. You can also report side effects directly via the Yellow Card scheme. By reporting side effects you can help provide more information on the safety of this medicine.

This medicine can be given as an infusion (drip) into a vein or a subcutaneous injection. It is likely that it will be given more than once a day, however, tell your doctor or nurse if you have any concern.

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United Kingdom
Perigord No: 302048
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