

Glyceryl Trinitrate 1 mg/ml solution for infusion

Read all of this leaflet carefully before you receive this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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

In this leaflet:

1. What Glyceryl Trinitrate is and what it is used for
2. Before you receive Glyceryl Trinitrate
3. How to use Glyceryl Trinitrate
4. Possible side effects
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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. Before you receive Glyceryl Trinitrate

This medicine must NOT be given to you if any of the following applies (tell your doctor):

- if you are allergic (hypersensitive) to nitrate medicines.
- if you are taking a medicine for the treatment of erectile dysfunction (e.g. sildenafil 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 must not receive Glyceryl Trinitrate if you are suffering from:

- shock (a life-threatening medical condition where insufficient blood flow reaches the body tissues)
- severe anaemia (lack of red blood cells)
- bleeding in the brain
- low blood oxygen (this can make you feel fatigued and short of breath) and angina attack caused by a heart disease where the muscle mass of the left heart ventricle is enlarged
- severe blood loss
- head injury
- inflammation and swelling of the covering of the heart

- compression of the heart caused by blood or fluid accumulation in the space between the heart muscle and the outer covering of the heart
- fluid accumulation in the lung

Take special care with Glyceryl Trinitrate

You will be treated by a health care professional experienced in using this kind of treatment.

Please, tell your doctor or pharmacist if any of the following apply to you:

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

Children

This medicine is not recommended in children.

Taking other medicines

Please tell your doctor, if you are taking or have taken any other medicines including medicines you can get without a prescription.

Glyceryl Trinitrate may interfere with the effects of drugs:

- which lower blood pressure (e.g. diltiazem, hydralazine, minoxidil)
- like certain antidepressants (tricyclics e.g. amitriptyline, nortriptyline, clomipramine, imipramine)
- like very strong pain killers which are similar to morphine (opioids e.g. alfentanil)

Pregnancy and breast-feeding

You should not receive this medicine if you are pregnant or breast-feeding unless considered essential by your doctor. Ask your doctor or pharmacist for advice before this medicine is given to you.

Driving and using machines

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

3. How to use Glyceryl Trinitrate

Usually 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 diluted solution for (intravenous) infusion.

- 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.

Dosage in adults and the elderly:

- **unresponsive congestive heart failure** (a condition in which the heart is not able to pump enough blood to meet the oxygen demands of the body), **acute myocardial infarction** (heart attack) and **left-sided heart failure**
 - The usual doses are: 10-100 micrograms per minute administered as a continuous intravenous infusion with frequent monitoring of blood pressure and heart rate.
- **refractory unstable angina pectoris** (angina attack with chest pain)
 - An initial infusion rate of 10-15 micrograms per minute is recommended.
- **use in surgery**
 - An initial infusion rate of 25 micrograms per minute is recommended; this should be increased gradually until the desired systolic arterial blood pressure is reached. The usual dose is 25-200 micrograms per minute.

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 discoloration 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.

The frequency of side effects is classified into the following categories: very common (more than 1 in 10 patients), common (fewer than 1 in 10 patients), uncommon (fewer than 1 in 100 patients), rare (fewer than 1 in 1,000 patients) and very rare (fewer than 1 in 10,000 patients), not known (cannot be estimated from the available data).

The following side effects have been reported:

Nervous system disorders

Very common: headache (particularly if the infusion is administered too rapidly)

Cardiac disorders

Common: fall or change in heart rate

Uncommon: faster heart rate

Vascular disorders

Very common: low blood pressure (hypotension)

Common: dizziness

(particularly if the infusion is administered too rapidly)

Gastrointestinal disorders

Common: nausea

Not known: pain in the chest

General disorders and administration site conditions

Not known: pain in the abdomen, restlessness, sweating, flushing

If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store Glyceryl Trinitrate

Keep out of the reach and sight of children.

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

The nurse or doctor will check that the medicine is not given to you 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.

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

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. Further 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
- 1 vial with 50 ml
- 10 ampoules with 10 ml
- 10 vials with 50 ml
- 10 ampoules with 25 ml
- 25 vials with 50 ml

Not all pack sizes may be marketed.

Marketing Authorisation Holder:

hameln pharma plus gmbh
Langes Feld 13
31789 Hameln, Germany

Manufacturer:

hameln pharmaceuticals gmbh
Langes Feld 13
31789 Hameln, Germany

Distributor:

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