Glyceryl Trinitrate 1 mg/ml solution for infusion

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICAL PRODUCT
Glyceryl Trinitrate 1 mg/ml solution for infusion

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
1 ml contains:
- Glyceryl trinitrate 1 mg/ml
- Sodium chloride 5.25 mg/ml

3. HOW TO USE GLYCERYL TRINITRATE

1. Initial treatment

• If you are allergic to glyceryl trinitrate, sodium chloride or any of the excipients, do not take this medicine.

2. What you need to know before you receive Glyceryl Trinitrate

- Contraindications

• Hypersensitivity to the active substance, other nitrates or any of the excipients
- Pregnancy

• Caution should be exercised in patients with arterial hypoxaemia (oxygen saturation less than 90%), severe liver or renal impairment, heart failure or acute myocardial infarction (heart attack).

• Elderly population

• The safety and efficacy of Glyceryl Trinitrate has not yet been established in infants.

3. How to use Glyceryl Trinitrate

• An initial dose of 10 mcg/min is recommended with increments of 20-25 mcg/min until the blood pressure is stabilised.

• Doses between 10-200 mcg/min have been required in some cases.

• The blood pressure lowering effect of Glyceryl Trinitrate will be increased if used together with phosphodiesterase inhibitors.

• Caution should be exercised in patients with arterial hypoxaemia (oxygen saturation less than 90%), severe liver or renal impairment, heart failure or acute myocardial infarction (heart attack).

4. Interaction with other medicinal products and other forms of interaction

• Concurrent administration of Glyceryl Trinitrate with acetyl salicylic acid may diminish the therapeutic response of Glyceryl Trinitrate.

• Trinitrate may increase the blood level of dihydroergotamine and its effect. This warrants special attention in patients with coronary artery disease, because dihydroergotamine antagonises the effect of Glyceryl Trinitrate.

• The use of vasoconstrictor-containing products (e.g., sufentanil) may diminish the therapeutic response of Glyceryl Trinitrate.

• In patients with heart failure, vardenafil, tadalafil.

• The use of sympathomimetic amines (stimulants) is contraindicated.

5. Directions of storage

• This medicinal product is not intended for use during transport or in any other circumstances where it is exposed to light or temperature extremes.

6.ワイド

• The product is only used in hospitals and is given to you by a doctor or nurse.

7. Clinical expertise

• The doctor and the nurse will discuss with you all the possible ways to use Glyceryl Trinitrate and will also discuss with you the potential benefits and risks of the medicine.

• The patient should be informed of the side effects of Glyceryl Trinitrate and the possibility of discontinuing treatment.

• The doctor and the nurse will explain the importance of using Glyceryl Trinitrate as directed and will also discuss with you the potential benefits and risks of the medicine.

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3. PATIENT INFORMATION

3.1. CONTRAINDICATIONS

This medicinal product is contraindicated in the following situations:

- Hypersensitivity to Glyceryl Trinitrate
- Headache
- A decrease in bleeding tendency in cases of thrombocytopenia
- Blood dyscrasias

3.2. PRECAUTIONS FOR USE

3.2.1. General

- Glyceryl Trinitrate is contraindicated in patients with coronary artery disease and in patients with a history of angina pectoris or myocardial infarction.
- It is not given by bolus injection.
- To ensure a constant infusion rate, Glyceryl Trinitrate should be administered into a central vein.
- If not used immediately, in-use storage times and shelf life should be observed.

3.3. ADVERSE REACTIONS

3.3.1. General

- The most common adverse reaction is hypotension.
- Other adverse reactions include: headache, dizziness, weakness, vomiting, nausea, flushing, skin irritation, and rash.

3.3.2. Cardiac

- Bradycardia
- Palpitations
- Chest pain

3.3.3. Vascular

- Hypotension
- Circulatory collapse

3.3.4. Gastrointestinal

- Nausea
- Vomiting

3.3.5. Skin and disorders

- Exfoliative rash
- Generalized erythema

3.3.6. Respiratory

- Shortness of breath

3.3.7. Other

- Irritation of the mouth, throat, and gums

3.4. OVERDOSAGE

3.4.1. General

- If overdose occurs, emetics may be administered. If necessary, supportive and symptomatic treatment should be given.

3.4.2. Cardiac

- If an idiopathic hypotension occurs, the underlying cause should be determined and treated.
- If a reaction is due to the drug, supportive and symptomatic treatment should be given to stabilize the patient.

3.4.3. Vascular

- If a reaction is due to the drug, supportive and symptomatic treatment should be given to stabilize the patient.

3.4.4. Gastrointestinal

- If a reaction is due to the drug, supportive and symptomatic treatment should be given to stabilize the patient.

4. PHARMACOLOGICAL PROPERTIES

4.1. Mechanism of Action

Glyceryl trinitrate is a vasodilator that acts by releasing nitric oxide. Nitric oxide is a free radical that activates the enzyme guanylate cyclase in the smooth muscle cells of blood vessels, causing the production of cyclic guanosine monophosphate (cGMP), which leads to the relaxation of smooth muscles, resulting in vasodilation.

4.2. Effects on the Cardiovascular System

Glyceryl trinitrate relaxes smooth muscles cells in other organs, including coronary arteries, where it produces a reduction in vascular resistance. This results in an increase in coronary blood flow and a decrease in myocardial oxygen demand.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacokinetics

5.1.1. Absorption

Glyceryl trinitrate is well absorbed when given sublingually. Peak plasma concentrations are usually achieved within 5-15 minutes after administration.

5.1.2. Distribution

Glyceryl trinitrate is widely distributed throughout the body, with high concentrations found in the coronary arteries and the heart muscle.

5.1.3. Metabolism

Glyceryl trinitrate is metabolized in the liver by a cytochrome P450-dependent pathway, resulting in the formation of inactive metabolites.

5.1.4. Elimination

Glyceryl trinitrate is primarily excreted unchanged in the urine, with a half-life of approximately 5-10 minutes.'