Noradrenaline (Norepinephrine) 0.08 mg/ml, solution for infusion

Noradrenaline

Package leaflet: Information for the user

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 or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet
1. What Noradrenaline 0.08 mg/ml, solution for infusion is and what it is used for
2. What you need to know before you use Noradrenaline 0.08 mg/ml, solution for infusion
3. How to use Noradrenaline 0.08 mg/ml, solution for infusion
4. How to stop Noradrenaline 0.08 mg/ml, solution for infusion
5. Possible side effects
6. Contents of the pack and other information

1. WHAT NORADRENALINE 0.08 MG/ML, SOLUTION FOR INFUSION IS AND WHAT IT IS USED FOR
Noradrenaline 0.08 mg/ml, solution for infusion is a medicine that belongs to the group of adrenergic and dopaminergic agents.
Noradrenaline 0.08 mg/ml, solution for infusion is indicated in adults weighing over 50 kg for the on-going treatment of hypotensive emergencies with escalating noradrenaline dose requirements.
The product is for adults only.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE NORADRENALINE 0.08 MG/ML, SOLUTION FOR INFUSION
- Elderly patients
- Patients with renal- and hepatic impairment.

Special precautions for use

In the event of adverse reactions linked to an excessive dosage, it is recommended to reduce the dosage if possible.
Perfusion of noradrenaline must be performed with continuous monitoring of blood pressure and cardiac frequency.
Caution is advised in patients with hyperthyroidism or diabetes mellitus.
Noradrenaline 0.08 mg/ml, solution for infusion is indicated for adults only.
Elderly patients
- if you have angina pectoris, or any vascular blockage in your limbs or abdomen (acute difficulty for the blood to circulate normally).
- if you have cardiac rhythm disorders (your heart beats too fast, too slow or irregular).
- if you have hyperthyroidism (your thyroid gland is overactive) or diabetes mellitus,
- if you are hypertensive (have low blood pressure) that has been caused by hypovolaemia (low blood volume),
- if you have angina pectors, or any vascular blockage in your limbs or abdomen (acute difficulty for the blood to circulate normally),

During the infusion of noradrenaline, your doctor will check continuously your blood pressure, cardiac frequency (heart rate) and the infusion site.
In cases where it is necessary to administer Noradrenaline at the same time as blood or plasma transfusion, the latter will be administered in a separate drip.
Children and adolescents
Noradrenaline (Norepinephrine) 0.08 mg/ml, solution for infusion is indicated for adults only.
Other medicines and Noradrenaline 0.08 mg/ml, solution for infusion

Noradrenaline 0.08 mg/ml, solution for infusion contains sodium
This product contains 17.7 mg of sodium per 50 ml vial. This should be taken into consideration by patients on a controlled sodium diet.

3. HOW TO USE NORADRENALINE 0.08 MG/ML, SOLUTION FOR INFUSION
Noradrenaline 0.08 mg/ml, solution for infusion will be given to you in a hospital, by a doctor or nurse.

Noradrenaline (Norepinephrine) 0.08 mg/ml, solution for infusion should not be diluted before use: it is ready to use solution in a 50 ml vial.
Noradrenaline solution for infusion will be administered by intravenous infusion (into a vein) and only via a central venous catheter. A syringe driving pump will be used.
The dose of Noradrenaline 0.08 mg/ml, solution for infusion will depend on your condition. Your doctor will know the best dose to use.
Noradrenaline 0.08 mg/ml, solution for infusion should not be used for initiating vasopressor treatment. It may be considered for use in patients already established on noradrenaline therapy whose dose requirements are clinically confirmed to be escalating, such that Noradrenaline 0.08 mg/ml solution for infusion may be commenced at a flow rate of 2 ml/hr.
The dose will be adjusted using the syringe driving pump according to the response to treatment, with the aim to establish a normal blood pressure.
The infusion site will be checked frequently.

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The infusion site will be checked frequently.
For single use only. Discard any unused contents.

If you use more Noradrenaline 0.08 mg/ml solution for infusion than you should

In the event of overdose, the following symptoms may be observed: cutaneous vasoconstriction (blood vessels become narrower), bed sores (skin ulcers), circulatory collapse (failure of the circulation) and hypertension (high blood pressure).

In the event of adverse reactions linked to an excessive dosage, contact your doctor immediately. It is recommended to reduce the dosage, if possible.

If you have any further questions on the use of this medicine, ask your doctor or nurse.

4. POSSIBLE SIDE EFFECTS

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

The following side effects have been reported:

- Anxiety
- Headache, tremor,
- Acute glaucoma,
- Tachycardia (fast heart rate), bradycardia (slow heart rate), arrhythmia (irregular heart beat), palpitations, increase in the contractility of the cardiac muscle, acute cardiac insufficiency (heart failure),
- Atrial hypertension (high blood pressure) and tissue hypoxia (decrease in oxygen supply to some organs); coldness and paleness of the members and the face,
- Respiratory insufficiency or difficulty, dyspnea (difficulty to breath),
- Vomiting,
- Retention of urine,
- Locally: possibility of irritation and necrosis (cell injury, causing death of cells in the tissue) at the injection site.

The continuous administration of vasopressor to maintain blood pressure in the absence of blood volume replacement may cause the following symptoms:

- severe peripheral and visceral vasoconstriction,
- decrease in renal blood flow,
- decrease in urine production,
- hypoxia,
- increase in lactate serum levels.

In case of hypersensitivity or overdose, the following effects may appear more frequently: arterial hypertension (high blood pressure), photophobia (abnormal intolerance to visual perception of light), retrosternal pain (thoracic pain), pharyngeal pain (throat pain), pallor, intense sweating and vomiting.

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5. HOW TO STORE NORADRENALINE 0.08 MG/ML, SOLUTION FOR INFUSION

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

By reporting side effects, you can help provide more information on the safety of this medicine.

5. CONTENTS OF THE PACK AND OTHER INFORMATION

What Noradrenaline Solution for infusion contains:

The active substance is Noradrenaline (norepinephrine) tartrate.

Each ml of solution contains 0.16 mg Noradrenaline tartrate equivalent to 0.08 mg Noradrenaline base. Each 50 mL vial contains 8 mg Noradrenaline tartrate, equivalent to 4 mg Noradrenaline base.

The other ingredients are: sodium chloride, disodium edetate dehydrate, hydrochloric acid or sodium hydroxide (pH adjustment), water for injections.

What Noradrenaline 0.08 mg/ml solution for infusion looks like and contents of the pack:

Clear, colourless or slightly yellow solution - pH = 3.2 – 3.8 – Osmolality: 260 - 320 mOsm/kg.

Posology and method of administration

For intravenous use only.

Noradrenaline 0.08 mg/ml solution for infusion should not be used for initiating vasopressor treatment. It may be considered for use in patients already established on noradrenaline therapy whose dose requirements are clinically confirmed to be escalating, such that Noradrenaline 0.08 mg/ml solution for infusion may be commenced at a flow rate of 2 ml/hr.

Noradrenaline should only be administered as an intravenous infusion via a central venous catheter to minimize the risk of extravasation and subsequent tissue necrosis. Noradrenaline (norepinephrine) 0.08 mg/ml solution for infusion should be infused at a controlled rate using a syringe driver pump.

Noradrenaline (norepinephrine) 0.08 mg/ml solution for infusion should not be diluted before use: it is supplied ready to use. It should not be mixed with other medicines.

Blood pressure control:

Blood pressure should be monitored carefully for the duration of therapy, and preferably controlled by arterial blood pressure monitoring. The patient should be monitored carefully for the duration of noradrenaline (norepinephrine) therapy.

Posology

Initial dose:

The initial dose of noradrenaline base is usually between 0.05-0.15 micrograms/kg/min.

Maintenance dose range:

The recommended maintenance range of noradrenaline base is between 0.05-1.5 micrograms/kg/min.

The following information is intended for medicinal and healthcare professionals only:

This is an extract from the Summary of Product Characteristics to assist in the administration of Noradrenaline (Norepinephrine) 0.08 mg/ml solution for infusion. When determining appropriateness of use in a particular patient, the prescriptor should be familiar with the Summary of Product Characteristics of the product.

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Each ml of solution for infusion contains 3.546 mg equivalent to 0.1542 mmol of sodium.

Each 50 mL vial contains approximately 177.3 mg equivalent to 7.71 mmol of sodium.

List of excipients: Sodium chloride, Disodium edetate dehydrate, Hydrochloric acid or Sodium hydroxide (pH adjustment), Water for injections.

Description of solution

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