

Package leaflet : Information for the user

Noradrenaline

(Norepinephrine) 0.25 mg/mL, solution for infusion

Noradrenaline / Norepinephrine



Referred to as Noradrenaline Solution for infusion in this leaflet.

- 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 Solution for infusion is and what it is used for
 2. What you need to know before you use Noradrenaline Solution for infusion
 3. How to use Noradrenaline Solution for infusion
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1. WHAT NORADRENALINE SOLUTION FOR INFUSION IS AND WHAT IT IS USED FOR

Noradrenaline Solution for infusion is a medicine that belongs to the group of adrenergic and dopaminergic agents. Noradrenaline 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 SOLUTION FOR INFUSION

- Do not use Noradrenaline Solution for infusion:**
- administred via peripheral cannula and/or peripheral vein.
 - if you are allergic to noradrenaline or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or nurse before using Noradrenaline Solution for infusion:

- if you have major left ventricular dysfunction (a heart condition),
- if you have recently had myocardial infarction (a heart attack),
- 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 hypotensive (have low blood pressure) that has been caused by hypovolaemia (low blood volume),
- if you have angina pectoris, 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) 0.25 mg/mL solution for infusion is indicated for adults only.

Other medicines and Noradrenaline Solution for infusion

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines, such as:

- some anaesthetic gas (halogen),
- some antidepressants (imipramine, serotoninerigic-adrenergics such as venlafaxine or duloxetine, monoamine oxidase inhibitors such as moclobemide or phenelzine),
- linezolid (an antibiotic),
- Methylene Blue.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, ask your doctor or nurse for advice before using this medicine. If you are pregnant, your doctor will decide if you should be given Noradrenaline Solution for infusion, as noradrenaline may harm the unborn baby. No information is available on the use of noradrenaline during lactation.

Noradrenaline Solution for infusion contains sodium

This product contains 177.3 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 SOLUTION FOR INFUSION

Noradrenaline Solution for infusion will be given to you in a hospital by a doctor or nurse. Noradrenaline (Norepinephrine) 0.25 mg/mL solution for infusion should not be diluted before use: it is a 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 driver pump will be used. The dose of Noradrenaline Solution for infusion will depend on your condition. Your doctor will know the best dose to use. Noradrenaline 0.25mg/ml solution for infusion should not be used for initiating vasopressor treatment. It may be considered for use in patients already established on noradrenaline whose dose requirements are clinically confirmed to be escalating, such that Noradrenaline 0.25 mg/mL may be commenced at a flow rate of 2 ml/h. The dose will be adjusted using the syringe driver pump according to the response to treatment, with the aim to establish a normal blood pressure. The infusion site will be cheked frequently.

For single use only. Discard any unused contents.

If you use more Noradrenaline 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 beats), palpitations, increase in the contractility of the cardiac muscle, acute cardiac insufficiency (heart failure),
- Arterial hypertension (high blood pressure) and tissue hypoxia (decrease in oxygen supply to some organ), 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.

Reporting of side effects

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system:

HPRA Pharmacovigilance

Earlsfort Terrace

IRL - Dublin 2

Tel: +353 1 6764971

Fax: +353 1 6762517

Website: www.hpra.ie

e-mail: medsafety@hpra.ie

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

5. HOW TO STORE NORADRENALINE SOLUTION FOR INFUSION

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

Do not use this medicine after the expiry date which is stated on the label of the vial and the carton after EXP.The expiry date refers to the last day of that month.

After the first opening, the product should be used immediately.

Do not store above 25 °C. Store the vial in the outer carton to protect from light.

Do not use this medicine if the solution is darker than slightly yellow or pink in colour or if it contains a precipitate.

Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. 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 0.5 mg Noradrenaline tartrate equivalent to 0.25 mg Noradrenaline base. Each 50 mL vial contains 25 mg Noradrenaline tartrate, equivalent to 12.5 mg Noradrenaline base.
- The other ingredients are: sodium chloride, disodium edetate dihydrate, hydrochloric acid or sodium hydroxide (pH adjustment) and water for injections.

What Noradrenaline Solution for infusion looks like and contents of the pack:

Clear colourless or slightly yellow solution for infusion packaged in a clear glass vial of 50 mL.

Pack sizes of 1, 10 and 25 vials.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

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1 rue Alexander Fleming

69007 LYON - France

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