Package leaflet: Information for the user

# Noradrenaline

## (Norepinephrine) 0.08 mg/ml solution for infusion

noradrenaline (norepinephrine)

AGUETTANT

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
4. Possible side effects
5. How to store Noradrenaline Solution for infusion
6. Contents of the pack and other information


## 1. What Noradrenaline Solution for infusion is and what it is used for

This medicine contains the active substance noradrenaline and act as a vasoconstrictor.
This medicine is only indicated for adults. This medicine is used in adults weighing over 50 kg for the on-going treatment of hypotensive emergencies that require an immediate increase in blood pressure to a normal level, and where noradrenaline dose requirements escalate.

## 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),
- if you have 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**

This medicine 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, serotoninergic-adrenergics such as venlafaxine or duloxetine, monoamine oxidase inhibitors such as moclobemide or phenelzine),
- linezolid (an antibiotic),
- Methylene Blue (methemoglobinemia antidote).

**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 this medicine, 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 medicine contains 177.3 mg sodium (main component of cooking/table salt) in each 50 ml vial. This is equivalent to 8.9 % of the recommended maximum daily dietary intake of sodium for an adult.

## 3. How to use Noradrenaline Solution for infusion

This medicine will be given to you in a hospital, by a doctor or nurse.
This medicine will be administered by intravenous infusion (into a vein) and only via a central venous catheter.
The dose of this medicine will depend on your condition. Your doctor will know the best dose to use.
This medicine 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.

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**The following information is intended for medical or 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 prescriber should be familiar with the Summary of Product Characteristics of the product.

**Therapeutic indications**

This medicine is indicated in adults weighing over 50 kg for the on-going treatment of hypotensive emergencies with escalating noradrenaline dose requirements.

**Posology and method of administration**

This medicine may be considered for use in patients already established on noradrenaline therapy whose dose requirements are clinically confirmed to be escalating, such that it may be commenced at a flow rate of 2 ml/h.
Noradrenaline should only be administered as an intravenous infusion via a central venous catheter. It should be infused at a controlled rate using an infusion pump, without dilution: it is supplied ready to use.
Blood pressure should be monitored carefully for the duration of 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.

**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, painful and cold extremities (gangrene),
- 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
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. Keep the vial in the outer carton in order 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).
  Each ml of solution contains 0.16 mg noradrenaline (norepinephrine) tartrate equivalent to 0.08 mg noradrenaline (norepinephrine) base.
  Each 50 ml vial contains 8 mg noradrenaline (norepinephrine) tartrate, equivalent to 4 mg noradrenaline (norepinephrine) base.
- The other ingredients are: sodium chloride, disodium edetate, 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.

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Detailed information on this medicinal product is available on the web site of the Health Products Regulatory Authority.

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*Titration of dose:*
Once an infusion of noradrenaline has been established the dose should be titrated in steps of 0.05-0.1 micrograms/kg/min of noradrenaline base according to the pressor effect observed. The aim should be to establish a low normal systolic blood pressure (100 - 120 mm Hg) or to achieve an adequate mean arterial blood pressure (greater than 65 mm Hg - depending on the patient's condition).

*Duration of Treatment:*
The treatment should be continued until high-dose vasoactive drug support is no longer indicated, at which point, the infusion should be gradually decreased, then switched to an infusion of lower concentration. Abrupt withdrawal can result in acute hypotension.

**Overdose**
In the event of overdose, the following may be observed: cutaneous vasoconstriction, bed sores, circulatory collapse, and hypertension.
In the event of adverse reactions linked to an excessive dosage, it is recommended to reduce the dosage if possible.

**Instructions for use and handling and disposal**
This medicine should not be used if the solution is darker than slightly yellow or pink in colour or if it contains a precipitate.
This medicine should not be used if it is not clear and contains particles, or if the tamper evident sealed vial is not intact.
This medicinal product must not be mixed with other medicinal products.
For single use only.
This medicine is already diluted and ready to use. It should be used without prior dilution. It should be used with a suitable infusion pump capable of accurately and consistently delivering the minimum specified volume at a strictly controlled rate of infusion in line with the dose titration instructions.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.