Package leaflet: Information for the user

Noradrenaline

(Norepinephrine) 0.08 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, pharmacist 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, pharmacist 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

This medicine contains the active substance noradrenaline and acts as a vasoconstrictor.
This medicine is only indicated for adults.
This medicine is used in adults weighing over 50 kg for the treatment of hypotensive emergencies that require an immediate increase in blood pressure to a normal level.

2. What you need to know before you are given Noradrenaline Solution for infusion

You must not be given Noradrenaline Solution for infusion:
- administered 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),
- if you are taking some anaesthetics such as halothane or cyclopropane (this may increase the risk of irregular heart beat).

Warnings and precautions

Talk to your doctor, pharmacist, or nurse before you are given Noradrenaline Solution for infusion if you:
- have major left ventricular dysfunction (a heart condition),
- have coronary (blood clot inside a blood vessel of the heart), mesenteric (blood clot in a vein that drains blood from the intestine), or peripheral vascular thrombosis (blood clot in the vein of arm or leg),
- have hypotension (low blood pressure) following myocardial infarction (heart attack),
- have Prinzmetal's variant angina,
- have heart rhythm disorders during your treatment,
- have hyperthyroidism (thyroid gland problem),
- have diabetes mellitus.

Additional monitoring tests that you may be required to undergo during treatment:
Your blood pressure and heart rate will be checked frequently during your treatment to avoid hypertension (high blood pressure).
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

The safety and efficacy of norepinephrine in children less than 18 years of age has not been established. Therefore, use in children is not recommended.

Other medicines and Noradrenaline Solution for infusion

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
The following medicines may influence the effect of Noradrenaline Solution for infusion:
- **Halothane, cyclopropane**, chloroform, enflurane or other halogenated anaesthetics are contraindicated (see section 2 of this leaflet, subsection "you must not be given"): these medicines are anaesthetics, they cause insensibility to pain and are used before some operations. If you are taking these medicines as well as noradrenaline (norepinephrine) this may increase the risk of irregular heart beat.
- **Amitriptiline, imipramine, trimipramine, moclobemide, iproniazide, phenelzine, fluoxetine, sertraline, desipramine:** these medicines are used for treatment of depression. Taking any of these medicines together with noradrenaline (norepinephrine) can dangerously increase its concentration in the blood and therefore its pressor action.
- **Digitalis glycosides** may occasionally cause irregular heart beat.
- **Levodopa** may enhance the effects of noradrenaline (norepinephrine).
- **Non-selective MAO inhibitors** (or within 14days of cessation of such therapy): increase in the pressor action of the sympathomimetic which is usually moderate. Should only be used under close medical supervision.
- **Selective MAO-A inhibitors:** by extrapolation from non-selective MAO inhibitors, risk of increase in the pressor action. Should only be used under close medical supervision.
- **Linezolid** (an antibiotic), (medicine used to treat infections caused by bacteria and other microorganisms), can dangerously increase noradrenaline (norepinephrine) concentration in the blood and therefore its pressor action, when taken together.
- **Methylene Blue** (methemoglobinemia antidote).
- **Alpha 1 agonists (e.g. midodrine):** if you are taking these medicines as well as noradrenaline (norepinephrine) this may increase the risk of pronounced hypertension (high blood pressure).
- **Alpha 1 blockers (e.g. prazosine, terazosine or doxazosine):** if you are taking these medicines as well as noradrenaline (norepinephrine) this may reduce the pressure action of norepinephrine.
- **Beta-blockers:** if you are taking these medicines as well as noradrenaline (norepinephrine) this may increase the risk of severe hypertension (high blood pressure).
- **Thyroid hormones:** if you are taking these medicines as well as noradrenaline (norepinephrine) this may cause increased cardiac (heart) effects.
- **Ergot alkaloids specifically those with relevant alpha1-agonistic action (e.g. ergotamine, dihydroergotamine, methylergometrine):** may enhance the vasopressor and vasoconstrictive (increasing blood pressure) effects.

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 50kg for the treatment of hypotensive emergencies.

Posology and method of administration

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 or a syringe 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.
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).

108606

- **Lithium** decreases the effect of noradrenaline (norepinephrine).
- **Reserpine, amphetamine:** may enhance the effects of noradrenaline (norepinephrine).

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 you are given Noradrenaline Solution for infusion

Dosage
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).
The dose of this medicine will depend on your condition. Your doctor will know the best dose to use.

If you are given more Noradrenaline Solution for infusion than you should
It is unlikely that you will receive too much as this medicine will be given to you in hospital. However, talk to your doctor or nurse if you have any concerns.
Symptoms that may occur if you are given too much noradrenaline are severe high blood pressure, slow heartbeat, violent headache, light sensitivity, pain in the chest, bleeding in the brain, pallor, fever, intense sweating and vomiting, fluid in the lungs causing breathlessness.
If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.
The frequency of the listed side effects is not known (frequency cannot be estimated from the available data).
Tell your doctor or nurse **immediately** if you experience:
- difficulty or irregularity in breathing,
- fast, slow, or irregular heart rate, palpitations,
- pain in the chest or throat.

Tell your doctor or nurse as soon as possible if you experience:
- anxiety,
- headaches, tremor,
- vomiting,
- high blood pressure,
- pallor (loss of skin colour), sweating, sensitivity to light,
- gangrene (painful and cold extremities that may become purple to very dark/ black, with tissue death),
- skin necrosis if the infusion is not given directly into the vein,
- acute glaucoma (eye issue),
- retention of urine.

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:
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.
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.

Marketing Authorisation Holder and Manufacturer
Laboratoire AGUETTANT
1 rue Alexander Fleming
69007 LYON
France

Distributed by:
AGUETTANT LTD
N°1, Farleigh House - Flax Bourton
BRISTOL - BS48 1UR
United Kingdom

This leaflet was last revised in 01/2026

Detailed information on this medicinal product is available on the web site of Medicines and Healthcare Products Regulatory Agency (MHRA).

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
Symptoms
Overdosage may result in headache, severe hypertension, reflex bradycardia, and decreased cardiac output.
These may be accompanied by violent headache, photophobia, retrosternal pain, pallor, fever, intense sweating, pulmonary oedema and vomiting.
The following may also be observed: cutaneous vasoconstriction, bed sores.
Treatment
In case of accidental overdose, as evidenced by excessive blood pressure elevation, discontinue the drug until the condition of the patient stabilizes.

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 or syringe 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.