



Package leaflet: Information for the user

Noradrenaline (Norepinephrine) 1 mg/ml concentrate for solution for infusion

noradrenaline (norepinephrine)



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 (Norepinephrine) is and what it is used for
2. What you need to know before you are given Noradrenaline (Norepinephrine)
3. How you are given Noradrenaline (Norepinephrine)
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1. What Noradrenaline (Norepinephrine) is and what it is used for

Noradrenaline (Norepinephrine) contains the active substance noradrenaline (norepinephrine). It causes narrowing of blood vessels (vasoconstriction).

Noradrenaline (Norepinephrine) is indicated in adults for the emergency restoration of blood pressure in cases of acute hypotension (low blood pressure).

2. What you need to know before you are given Noradrenaline (Norepinephrine)

You must not be given Noradrenaline (Norepinephrine)

- if you are allergic to noradrenaline (norepinephrine) or to any of the other ingredients of this medicine (listed in section 6);
- if you are hypotensive (have low blood pressure) that has been caused by hypovolaemia (low blood volume);
- 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 (Norepinephrine) 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 – you will need a reduced dose;
- have hyperthyroidism (thyroid gland problem);
- have diabetes mellitus;
- are elderly.

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).

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 (Norepinephrine)

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 (Norepinephrine):

- **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).
- **Antihistamines**, as some may block the intake of catecholamines by peripheral tissues and increase the toxicity of injected noradrenaline (norepinephrine).
- **Chlorpheniramine hydrochloride, tripeleminamine hydrochloride:** significantly increase the toxicity of noradrenaline (norepinephrine).
- **Non-selective MAO inhibitors (or within 14 days 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.
- **Alpha and 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, cardiac (heart) glycosides, anti-arrhythmics:** if you are taking these medicines as well as noradrenaline (norepinephrine) this may cause increased cardiac (heart) effects.
- **Ergot alkaloids or oxytocin** may enhance the vasoconstrictor and vasoconstrictive (increasing blood pressure) effects.
- **Desmopressin or vasopressin:** its antidiuretic effect is diminished.
- **Lithium** decreases the effect of noradrenaline (norepinephrine).
- **Guanethidine, guanadrel, reserpine, methyldopa or tricyclic antidepressants, amphetamine, doxapram, mazindol, rauwolfia alkaloids:** may enhance the effects of noradrenaline (norepinephrine).
- **Propofol:** Concomitant administration may lead to propofol infusion syndrome (PRIS).

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before this medicine is given to you. Noradrenaline may harm the unborn baby. Your doctor will decide if you should be given Noradrenaline.

The following information is intended for healthcare professionals only:

Method of administration

For intravenous use only, after dilution. For single use. The infusion should be at a controlled rate using either a syringe pump or an infusion pump or a drip counter.

Dilution instructions

This product should be visually inspected prior to administration. Only a clear, colourless or slightly yellowish solution, free of particles or precipitates should be used. Do not use ampoules with a pink colour or darker than pale yellow, or containing a precipitate.

Add 2 ml of Noradrenaline (Norepinephrine) to 48 ml 5% dextrose (or sodium chloride 9 mg/ml (0.9%), or isotonic dextrose saline) for administration by syringe pump.
Or add 20 ml of Noradrenaline (Norepinephrine) to 480 ml 5% dextrose (or sodium chloride 9 mg/ml (0.9%), or isotonic dextrose saline) for administration by drip counter.
When diluted, the final concentration of the infusion solution is usually 40 mg/l noradrenaline (norepinephrine) (equivalent to 80 mg/l noradrenaline (norepinephrine) tartrate).
If other dilutions are used check the calculation carefully before starting treatment.

It is not known whether this medicine is excreted in human milk. Because many medicines are excreted in human milk, caution should be exercised when norepinephrine is given to a nursing woman.

Driving and using machines

Since this medicine will be given to you in a hospital, your doctor will inform you when you will be able to drive or use machines.

Noradrenaline (Norepinephrine) contains sodium

This medicine contains 3.3 mg sodium (main component of cooking/table salt) in each ml. This is equivalent to 0.16 % of the recommended maximum daily dietary intake of sodium for an adult.

3. How you are given Noradrenaline (Norepinephrine)

Noradrenaline (Norepinephrine) will be given to you in a hospital by a doctor or nurse.

Dosage

Noradrenaline (Norepinephrine) is first diluted and then infused into a vein. It should not be mixed with other medicines. The dose of noradrenaline (norepinephrine) depends on the condition of the patient. Your doctor will know the best dose to use. The initial dose is 0.4 to 0.8 mg per hour of noradrenaline (norepinephrine) (equivalent to 0.8 to 1.6 mg per hour of noradrenaline (norepinephrine) tartrate). The dose can then be adjusted using a pump according to the response to treatment, with the aim to establish a normal blood pressure. Your doctor will monitor your blood pressure and blood volume.

If you are given more noradrenaline (norepinephrine) 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 (norepinephrine) 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, insomnia, confusion, headaches, psychotic state, weakness, tremor, lower vigilance, anorexia, nausea, 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),
- scarification of the skin, bluish skin colour, hot flushes or skin redness, skin rash, hives or itching,
- retention of urine.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via the 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 (Norepinephrine)

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 carton and ampoule label after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C. Keep the ampoule in the outer carton in order to protect from light.

Do not throw away any medicines via wastewater or household waste. 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 (Norepinephrine) contains

The active substance is noradrenaline (norepinephrine).

Each ml of concentrate for solution for infusion contains 2 mg noradrenaline (norepinephrine) tartrate, equivalent to 1 mg noradrenaline (norepinephrine).

Each ampoule of 4 ml contains 8 mg noradrenaline (norepinephrine) tartrate, equivalent to 4 mg noradrenaline (norepinephrine).

Each ampoule of 8 ml contains 16 mg noradrenaline (norepinephrine) tartrate, equivalent to 8 mg noradrenaline (norepinephrine).

The other ingredients are sodium chloride, sodium hydroxide or hydrochloric acid and water for injections.

What Noradrenaline (Norepinephrine) looks like and contents of the pack

Clear, colourless or slightly yellowish solution of pH 3.0 to 4.0 packaged in a clear glass ampoule of 4 ml or 8 ml.

Boxes of 10, 50 or 100 ampoules.

Not all pack sizes may be marketed.

Marketing Authorisation holder

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In absence of specific data, this medicinal product must not be mixed with other medicinal products.

After dilution: The physicochemical stability of diluted product (in 5% dextrose, sodium chloride 9 mg/ml (0.9%), or in an isotonic dextrose saline) has been demonstrated for 48 hours at 30°C.

However, from a microbiological point of view, the diluted product should be used immediately. If the product is not used immediately, the duration and conditions of use are the sole responsibility of the user.

Posology

Initial rate of infusion:

The initial rate of infusion should be between 10 ml/hour and 20 ml/hour (0.16 ml/min to 0.33 ml/min). This is equivalent to

0.4 mg/hr to 0.8 mg/h noradrenaline (norepinephrine) (equivalent to 0.8 mg/h to 1.6 mg/h noradrenaline (norepinephrine) tartrate).

Titration of dose:

Once an infusion of noradrenaline (norepinephrine) has been established the dose should be titrated according to the pressor effect observed. There is great individual variation in the dose required to attain and maintain normotension. 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 to 80 mm Hg – depending on the patient's condition).