

Noradrenaline (Norepinephrine) 1 mg/ml Concentrate for Solution for Infusion

Noradrenaline (as noradrenaline tartrate)

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, please ask your doctor or pharmacist.
- This medicine has been prescribed for you. 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 pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

The name of this medicinal product is Noradrenaline (Norepinephrine) 1 mg/ml Concentrate for Solution for Infusion but it will be referred to as Noradrenaline (Norepinephrine) Concentrate throughout this leaflet.

What is in this leaflet:

1. What Noradrenaline (Norepinephrine) Concentrate is and what it is used for
2. What you need to know before you are given Noradrenaline (Norepinephrine) Concentrate
3. How to use Noradrenaline (Norepinephrine) Concentrate
4. Possible side effects
5. How to store Noradrenaline (Norepinephrine) Concentrate
6. Contents of the pack and other information

1. What Noradrenaline (Norepinephrine) Concentrate is and what it is used for

Noradrenaline (Norepinephrine) Concentrate for Solution for Infusion is used in an emergency to increase blood pressure to normal levels.

It contains the active ingredient noradrenaline which belongs to a group of medicines called adrenergic and dopaminergic agents.

- supplying the heart, intestines, or other parts of the body
- low blood pressure following a heart attack
- a type of angina (chest pain) called Prinzmetal's angina
- are elderly.

Other medicines and Noradrenaline

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines.

A number of medicines are known to increase the toxic effects of noradrenaline, such as:

- monoamine oxidase inhibitors (antidepressants)
- tricyclic antidepressants
- linezolid (an antibiotic)
- anaesthetics (especially anaesthetic gases)
- adrenergic-serotonergic medicines, e.g. used in the treatment of asthma and heart conditions
- guanethidine.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Noradrenaline (Norepinephrine) Concentrate may harm the unborn baby. Your doctor will decide if you should be given Noradrenaline (Norepinephrine) Concentrate.

Noradrenaline (Norepinephrine) Concentrate contains sodium

This medicine contains 13.3 mg of sodium (main component of cooking/table salt) in each 4 ml ampoule and 33.3 mg of sodium in 10 ml ampoule. This is equivalent to 0.7% and 1.7% of the recommended maximum daily dietary intake of sodium for an adult, respectively. This medicine may be diluted with sodium-containing solutions. Take into consideration if you are on a low-sodium diet.

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

Do not take Noradrenaline (Norepinephrine) Concentrate:

- if you are allergic to noradrenaline preparations or to any of the other ingredients of this medicine (listed in section 6).

Tell your doctor if any of the above applies to you before this medicine is used.

Warnings and precautions

Talk to your doctor or pharmacist before taking Noradrenaline (Norepinephrine) Concentrate if you have:

- diabetes
- high blood pressure
- an over-active thyroid
- low levels of oxygen in the blood
- high levels of carbon dioxide in the blood
- clots or obstructions in the blood vessels

3. How to use Noradrenaline (Norepinephrine) Concentrate

Noradrenaline (Norepinephrine) Concentrate will be given to you in hospital by a doctor or nurse. It is first diluted and then infused into a vein.

The recommended dose of Noradrenaline (Norepinephrine) Concentrate will depend on your medical condition. The usual dose is between 0.4 and 0.8 mg per hour. Your doctor will determine the correct dose for you. After the initial dose your doctor will assess your response and adjust the dose accordingly.

If you are given more or forget to take Noradrenaline (Norepinephrine) Concentrate

It is unlikely that you will receive too much or too little of this medicine, as this medicine will be given to you in hospital.

Noradrenaline (Norepinephrine) 1 mg/ml Concentrate for Solution for Infusion

The following information is intended for healthcare professionals only:

For intravenous use.

Dilute before use.

Administer as a diluted solution via a central venous catheter. The infusion should be at a controlled rate using either a syringe pump, or an infusion pump or a drip counter.

Incompatibilities

Infusion solutions containing noradrenaline tartrate have been reported to be incompatible with the following substances: alkalis and oxidising agents, barbiturates, chlorpheniramine, chlorothiazide, nitrofurantoin, novobiocin, phenytoin, sodium bicarbonate, sodium iodide, streptomycin.

Dilution Instructions

For single use only. Discard any unused contents.

The solution should be visually inspected prior to use. The medicine should not be used if the solution contains visible particles/solids. Do not use the solution for infusion if it has a brown colour.

Dilute before use with one of these solutions (diluent): glucose 5% (w/v) solution, sodium chloride 0.9% (w/v) solution or sodium chloride 0.45% (w/v) with glucose 5% (w/v) solution.

Dilution ratios (e.g.):

- Add 2 ml of concentrate to 48 ml of solution (diluent).
- Add 4 ml of concentrate to 96 ml of solution (diluent).
- Add 10 ml of concentrate to 240 ml of solution (diluent).
- Add 20 ml of concentrate to 480 ml of solution (diluent).

In all cases the final concentration of the infusion solution is 40 mg/l noradrenaline (which is equivalent to 80 mg/l noradrenaline tartrate). Dilutions other than 40 mg/l noradrenaline may also be used. If dilutions other than 40 mg/l noradrenaline are used, check the infusion rate calculation carefully before starting treatment.

However, talk to your doctor or nurse if you have any concerns.

Symptoms of overdose are severe high blood pressure, slow heartbeat, violent headache, difficulty breathing due to fluids in the lungs, light sensitivity, pain in the chest, pale colour, intense sweating and vomiting.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Tell your doctor immediately if you experience:

- sudden itchy rash (hives), swelling of the hands, feet, ankles, face, lips, mouth or throat (which may cause difficulty in swallowing or breathing), feeling that you are going to faint.
- pain and/or swelling at the injection site.

Tell your doctor as soon as possible if you experience:

- slow heart rate
- abnormal heart rhythm
- breathing difficulties
- anxiety
- headaches
- cold extremities
- pain in the extremities.

Your doctor will monitor your blood pressure and blood volume.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: 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) Concentrate

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

Store below 25° C.

Keep the ampoule in the outer carton in order to protect from light.

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

Chemical and physical in-use stability has been demonstrated for 48 hours at 22 ± 2° C exposed to daily light cycles and 30° C for diluted concentrate in glucose 5% (w/v), sodium chloride 0.9% (w/v) and sodium chloride 0.45% (w/v) with glucose 5% (w/v). From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8° C, unless dilution has taken place in controlled and validated aseptic conditions.

The medicine should not be used if the solution contains visible particles/solids.

Do not use this medicine if the solution is brown in colour.

Do not throw away any medicines via wastewater. Ask your pharmacists 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) Concentrate contains

The active substance is noradrenaline (as noradrenaline tartrate).

1 ml of concentrate for solution for infusion contains 2 mg noradrenaline tartrate equivalent to 1 mg noradrenaline base.

Each 4 ml ampoule of concentrate for infusion contains 8 mg noradrenaline tartrate equivalent to 4 mg noradrenaline base.

Each 10 ml ampoule of concentrate for infusion contains 20 mg noradrenaline tartrate equivalent to 10 mg noradrenaline base.

The other ingredients are:

- Sodium chloride
- Disodium edetate
- Sodium hydroxide (for pH adjustment)
- Hydrochloric acid (for pH adjustment)
- Water for injections.

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

This medicinal product is presented as a concentrate for solution for infusion in a clear glass ampoule, hydrolytic class No. I. The solution is a clear colourless to yellowish concentrate for solution for infusion, free of any visible particles.

It is supplied in packs of 5, 10 or 50 ampoules containing 4 ml and 10 ampoules containing 4 ml.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Zentiva Pharma UK Limited,
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Manufacturer

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For information in large print, tape, CD or Braille, telephone 0800 198 5000.

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Shelf life after dilution

Chemical and physical in-use stability has been demonstrated for 48 h at 22 ± 2° C exposed to daily light cycles and 30° C for diluted concentrate in glucose 5% (w/v), sodium chloride 0.9% (w/v) and sodium chloride 0.45% (w/v) with glucose 5% (w/v) exposed to daily light cycles. Appearance of diluted solution has to be clear, colourless and free of visible particles.

From a microbiological point of view, the diluted product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8° C, unless dilution has taken place in controlled and validated aseptic conditions.

Any unused product or waste material should be disposed of in accordance with local requirements.