PACKAGE LEAFLET: INFORMATION FOR THE USER

Noradrenaline (Norepinephrine) 1mg/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

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

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 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-serotoninergic 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 less than 1 mmol sodium (23 mg) per ampoule, that is to say essentially 'sodium-free'. The 2 ml ampoule contains 6.7 mg sodium, and the 4 ml ampoule contains 13.3 mg sodium. This medicine may be diluted with sodium-containing solutions. Take into consideration if you are on a low-sodium diet.

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. 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.

Do not store above 25°C.

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.

From a microbiological point of view, the product should be used immediately after dilution.

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) contains

The active substance is noradrenaline (as noradrenaline tartrate).

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

1 ampoule of 2 ml contains 4 mg noradrenaline tartrate equivalent to 2 mg noradrenaline base.

1 ampoule of 4 ml contains 8 mg noradrenaline tartrate equivalent to 4 mg noradrenaline base.

The other ingredients are:

- sodium chloride (see section 2 “Noradrenaline (Norepinephrine) Concentrate contains sodium”)
- sodium hydroxide (for pH adjustment) (see section 2 “Noradrenaline (Norepinephrine) Concentrate contains sodium”)
- 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. The solution is a clear colourless or yellowish solution.

It may be supplied in packs of 5 x 2 ml ampoules or 5 x 4 ml ampoules.

Marketing Authorisation Holder
Hospira UK Limited
Walton Oaks
Walton-On-The-Hill
Dorking Road
Tadworth
Surrey
KT20 7NS
UK

Manufacturers
Avara Liscate Pharmaceutical Services S.p.A.
Via Fosse Ardeatine 2
20050 Liscate - Milan
Italy

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Finland and Sweden:	Noradrenalin Pfizer
United Kingdom (Northern Ireland):	Noradrenaline (Norepinephrine)

This leaflet was last revised in 03/2024.
Ref: gxNO 8_0

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
Dilute before use with glucose 5% solution or sodium chloride 9 mg/ml (0.9%) with glucose 5% solution.

Either add 2 ml of concentrate to 48 ml glucose 5% solution (or sodium chloride 9 mg/ml (0.9%) with glucose 5% solution) for administration by syringe pump, or add 20 ml of concentrate to 480 ml glucose 5% solution (or sodium chloride 9 mg/ml (0.9%) with glucose 5% solution) for administration by drip counter. In both cases the final concentration of the infusion solution is 40 mg/litre noradrenaline base (which is equivalent to 80 mg/litre noradrenaline tartrate). Dilutions other than 40 mg/litre noradrenaline base may also be used. If dilutions other than 40 mg/litre noradrenaline base are used, check the infusion rate calculation carefully before starting treatment.

The product is compatible with PVC infusion bags.

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

Shelf life after dilution
Chemical and physical in-use stability has been demonstrated for 24 hours at 25°C when diluted to 4 mg/litre and 40 mg/litre noradrenaline base in sodium chloride 9 mg/ml (0.9%) solution or glucose 5% solution. However, 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.