PACKAGE LEAFLET: INFORMATION FOR THE USER

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, ask your doctor or pharmacist
- 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 throughout this leaflet.

What is in this leaflet:

1. WHAT NORADRENALINE SOLUTION IS AND WHAT IT IS USED FOR

Noradrenaline is used in an emergency to increase blood pressure to normal levels.

2. WHAT YOU NEED TO KNOW BEFORE YOU START TO USE NORADRENALINE SOLUTION

You will not be given Noradrenaline 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 pharmacist before using Noradrenaline if you:
- have diabetes
- suffer from high blood pressure
- have an over-active thyroid
- have low levels of oxygen in the blood
- have high levels of carbon dioxide in the blood
- have clots or obstructions in the blood vessels supplying the heart, intestines, or other parts of the body
- have low blood pressure following a heart attack
- have a type of angina (chest pain) called Prinzmetal's angina
- are elderly
- are hypotensive (have a low blood pressure) that has been caused by hypovolaemia (low blood volume)
- are taking some anaesthetics such as halothane or cyclopropane (this may increase the risk of irregular heart beat).

Other medicines and Noradrenaline
Tell your doctor or pharmacist if you are taking, or have recently taken, 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.

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 or pharmacist for advice before taking this medicine. Noradrenaline may harm the unborn baby. Your doctor will decide if you should be given Noradrenaline.

Noradrenaline contains sodium
The 2 ml ampoule contains 6.6 mg sodium, the 4 ml ampoule contains 13.2 mg sodium, and the 20 ml vial contains 66.1 mg sodium.
To be taken into consideration by patients on a controlled sodium diet.

3. HOW TO USE NORADRENALINE SOLUTION

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

The initial dose of Noradrenaline will depend on your medical condition. The usual dose is between 0.4 mg 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 Noradrenaline 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 of overdose are severe high blood pressure, slow heartbeat, violent headache, 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 national reporting systems listed below:

Ireland:
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

- Keep out of the sight and reach of children
- Do not store above 25°C. Store in the original package to protect from light
- Do not use 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.
- This medicine should not be used if the solution is brown in colour
- 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) Concentrate 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.
1 vial of 20 ml contains 40 mg noradrenaline tartrate equivalent to 20 mg noradrenaline base.

The other ingredients are:
- sodium chloride
- sodium hydroxide (for pH adjustment)
- hydrochloric acid (for pH adjustment)
- water for injections.

What Noradrenaline (Norepinephrine) Concentrate looks like and contents of the pack
Noradrenaline (Norepinephrine) Concentrate is a clear, colourless or yellowish solution.

The product is presented in colourless glass ampoules and vials, in the following pack sizes:
- 5 ampoules of 2 ml in a pack
- 5 ampoules of 4 ml in a pack
- 5 vials of 20 ml in a pack.

Not all pack sizes may be marketed.

Marketing Authorisation Holder in Ireland:
Pinewood Laboratories Limited, Ballymacarbry, Clonmel, Co. Tipperary, Ireland

Manufacturer
Farma Mediterrania S.L., C/ Sant Sebastià, s/n, Sant Just Desvern (Barcelona)

Laboratorios Novocat Farma, S.A., Avda de les Flores, 29 local 7, 08191 Rubí. Barcelona, Spain

This medicinal product is authorised in the Member States of the EEA under the following names:

Ireland: Noradrenaline (Norepinephrine) 1 mg/ml Concentrate for solution for Infusion

This leaflet was last revised in 12/2020

INFORMATION FOR HEALTHCARE PROFESSIONALS
Noradrenaline (Norepinephrine) 1 mg/ml Concentrate for solution for infusion
Noradrenaline (as noradrenaline tartrate)

The following information is intended for medical or 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 bitartrate 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.