PATIENT INFORMATION LEAFLET

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. Even if you have already used Noradrenaline or a similar medicine before, we advise you to read this text carefully. The information may have been changed.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, 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 symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.
- 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.

In this leaflet:

1. What Noradrenaline (Norepinephrine) Concentrate is and what it is used for
2. Things to consider before you start to use Noradrenaline (Norepinephrine) Concentrate
3. How to use Noradrenaline (Norepinephrine) Concentrate
4. Possible side effects
5. How to store Noradrenaline (Norepinephrine) Concentrate
6. Further information

1. WHAT NORADRENALINE (Norepinephrine) CONCENTRATE IS AND WHAT IT IS USED FOR

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

2. THINGS TO CONSIDER BEFORE YOU START TO USE NORADRENALINE (Norepinephrine) CONCENTRATE

You will not be given Noradrenaline (Norepinephrine) Concentrate if
- You are allergic (hypersensitive) to Noradrenaline preparations or to any of the other ingredients of this medicine (see section 6).
Special care will be taken 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)

Taking other medicines
Please tell your doctor or pharmacist if you are taking, or have recently taken, any other medicines, including medicines obtained without a prescription. 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
Tell your doctor if you are pregnant or breast-feeding. Noradrenaline may harm the unborn baby. Your doctor will decide if you should be given Noradrenaline (Norepinephrine) Concentrate.

Ask your doctor or pharmacist for advice before taking any medicine.

The medicinal product must be stored out of the sight and reach of children.

Important information about one of the ingredients of Noradrenaline (Norepinephrine) Concentrate.

This medicinal product 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.
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 initial 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 Noradrenaline (Norepinephrine) Concentrate than you should be:**
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, Noradrenaline Novocat 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:

**United Kingdom:**
Yellow Card Scheme
Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)

**Ireland:**
HPRA Pharmacovigilance, Earlsfort Terrace
IRL - Dublin 2; Tel: +353 1 6764971
Fax: +353 1 6762517. Website: [www.hpра.ie](http://www.hpра.ie)
E-mail: med safety@hpра.ie.
By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE NORADRENALINE (Norepinephrine) CONCENTRATE

- 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 to protect the environment.

6. FURTHER 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.

Manufacturer and Marketing Authorisation Holder:

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Noradrenaline (Norepinephrine) Concentrate

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.