

## Package leaflet: Information for the user

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

#### 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, 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.

The name of this medicinal product is NORADRENALINE (NOREPINEPHRINE) 1 mg/ml Concentrate for solution for infusion, but will be referred as Noradrenaline (Norepinephrine) Concentrate throughout the whole 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 you are given 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 is a drug that belongs to the group of adrenergic and dopaminergic agent.

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

#### **2. What you need to know before you are given Noradrenaline (Norepinephrine) Concentrate** **You must not be given Noradrenaline (Norepinephrine) Concentrate:**

- if you are allergic to noradrenaline 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) Concentrate:

- if you have extravasation risk ;
- if you have major left ventricular dysfunction (a heart condition) ;
- if you have coronary, mesenteric or peripheral vascular thrombosis ;
- if you have hypotension following myocardial infarction ;
- if you have Prinzmetal's variant angina ;
- if you have heart rhythm disorders during your treatment – you will need a reduced dose ;

- if you have hyperthyroidism or diabetes mellitus ;
- if you are elderly.

Your blood pressure and heart rate will be checked frequently during your treatment to avoid hypertension.

### **Other medicines and Noradrenaline (Norepinephrine) Concentrate**

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

Noradrenaline (Norepinephrine) Concentrate may affect or be affected by other medicines. In particular, tell your doctor if you are taking any of the following:

- Halothane, cyclopropane: 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 this may increase the risk of irregular heart beat.
- Amitriptyline, Imipramine, Trimipramine, Moclobemide, Iproniazide, Phelzine, Fluoxetine, Sertraline: these medicines are used for treatment of depression. Taking any of these medicines together with Noradrenaline can dangerously increase its concentration in the blood and therefore its pressor action.
- Linezolid, an antibiotic (drug used to treat infections caused by bacteria and other microorganisms), can dangerously increase Noradrenaline 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 this may increase the risk of severe hypertension.
- Thyroid hormones, Cardiac glycosides, Anti-arrhythmics: if you are taking these medicines as well as Noradrenaline this may cause increased cardiac effects.
- Ergot alkaloids or oxytocin may enhance the vasopressor and vasoconstrictive effects.

### **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 you are given this medicine. Then your doctor will decide if you should be given this medicine.

### **Driving and using machines**

Since Noradrenaline 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) Concentrate contains sodium:**

This medicine contains less than 1 mmol sodium (23 mg) per 4 ml ampoule, that is to say essentially 'sodium-free'.

This medicine contains 26.4 mg sodium (main component of cooking/table salt) in each 8 ml ampoule. This is equivalent to 1.3 % of the recommended maximum daily dietary intake of sodium for an adult.

### **3. How you are given Noradrenaline (Norepinephrine) Concentrate**

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

### **Dosage**

The dose of Noradrenaline depends on the condition of the patient. Your doctor will know the best dose to use. Noradrenaline is first diluted and then usually infused into a vein. The dose can then be adjusted using a pump according to the response to treatment, with the aim to establish a normal blood pressure. The initial dose is 0.4 to 0.8 milligrams per hour of Noradrenaline (Norepinephrine) base.

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, Noradrenaline can cause side effects, although not everybody gets them. The following side effects have been reported:

- skin necrosis (death) if the infusion is not given directly into the vein,
- anxiety, insomnia, confusion, headaches, psychotic state, weakness, tremor, lower vigilance, anorexia, nausea, vomiting,
- difficulty in breathing, fast or slow heart rate, pain in the chest or throat,
- retention of urine,
- pallor (loss of skin colour), sweating, sensitivity to light.

### **Reporting of side effects**

If you get any side effects, talk to your doctor or your 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](http://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 use this medicine after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C. Store in the original package to protect from light.

#### After dilution:

The physicochemical stability of diluted product (in 5% dextrose or in an isotonic dextrose saline) has been demonstrated for 48 hours at 25°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.

Do not use if you notice any type of coloration.

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 tartrate.

Each ml of concentrate for solution for infusion contains 2 mg Noradrenaline tartrate, equivalent to 1 mg Noradrenaline base

Each 4ml ampoule contains 8mg Noradrenaline tartrate equivalent to 4mg Noradrenaline base.

Each 8ml ampoule contains 16mg Noradrenaline tartrate equivalent to 8mg Noradrenaline base.

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

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

Clear and colourless liquid 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 - Manufacturer**

Laboratoire Aguetant  
1 rue Alexander Fleming  
69007 LYON  
FRANCE

**Manufacturer**

DELPHARM Tours  
Rue Paul Langevin  
37 170 Chambray-Les-Tours  
France

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

Belgium: Noradrenaline (norepinephrine) Aguetant 1 mg/ml solution à diluer pour perfusion  
United kingdom: Noradrenaline (norepinephrine) 1 mg/ml concentrate for solution for infusion

**This leaflet was last revised in September 2018.**