

**Package leaflet: Information for the patient**

**Noradrenaline  
(Norepinephrine) Kabi  
1 mg/ml**

**concentrate for solution for infusion**  
noradrenaline (norepinephrine)

**Read all of this leaflet carefully before you are given 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 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 or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet:**

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

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

Noradrenaline (Norepinephrine) Kabi contains the active substance noradrenaline (norepinephrine) and acts as a vasoconstrictor (causes narrowing of blood vessels). Noradrenaline (Norepinephrine) Kabi is used in adults in an emergency to increase blood pressure to normal levels.

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

**You should not be given Noradrenaline (Norepinephrine) Kabi**

- if you are allergic to noradrenaline or any of the other ingredients of this medicine (listed in section 6).
- if you have low blood pressure that has been caused by low blood volume.
- if you are given the anaesthetic gases halothane or cyclopropane as this may increase the risk of irregular heartbeat.

**Warnings and precautions**

Talk to your doctor or nurse before you are given Noradrenaline (Norepinephrine) Kabi if you:

- have diabetes
- have liver or kidney impairment
- suffer from high blood pressure
- have an over-active thyroid gland
- have low levels of oxygen in the blood
- have high levels of carbon dioxide in the blood
- have elevated pressure inside the skull (intracranial pressure)
- 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 angina (chest pain), in particular Prinzmetal's angina
- have major left ventricular dysfunction
- recently had myocardial infarction (a heart attack)
- have cardiac rhythm disorders (your heart beats too fast, too slow or irregular), you will need a reduced dose
- are elderly

During the infusion of noradrenaline, your doctor will continuously check your blood pressure, cardiac frequency (heart rate), and the infusion site.

**Children and adolescents**

The safety and efficacy of noradrenaline in children and adolescents aged less than

18 years old has not been established. Therefore use in children and adolescents is not recommended.

**Other medicines and Noradrenaline (Norepinephrine) Kabi**

Tell your doctor if you are taking/using, have recently taken/used or might take/ use any other medicines.

It is particularly important if you use or have recently used any of the following medicines:

- medicines to treat depression called "monoamine oxidase inhibitors" that you take currently or have taken in the last 14 days
- medicines to treat depression called "tricyclic antidepressants" (e.g. imipramine or desipramine)
- linezolid (an antibiotic)
- anaesthetics (especially anaesthetic gases such as cyclopropane, halothane, chloroform, enflurane)
- adrenergic serotonergic medicines, e.g. used in the treatment of asthma and heart conditions
- medicines to treat high blood pressure (e.g. guanethidine, guanadrel, reserpine, methyldopa, alpha and beta-blockers)
- rauwolfia alkaloids
- medicines to treat heart rhythm disorders
- cardiac glycosides (to treat heart diseases)
- levodopa (to treat Parkinson's disease)
- thyroid hormones
- oxytocin (used to improve uterine contractions)
- antihistamines (for treating allergies, e.g. chlorpheniramine hydrochloride, tripelemine hydrochloride)
- amphetamine
- doxapram (for breathing disorders)
- mazindol (to treat obesity)
- medicines to treat migraine (ergot alkaloids)
- lithium (to treat some mental disorders)
- vasopressin, desmopressin (antidiuretics, to reduce urine production)

Using noradrenaline with propofol (an anaesthetic) may lead to propofol infusion syndrome (PRIS), which is a serious condition that affects patients who are being sedated with propofol in intensive care units. Your doctor would notice disorders in your body's metabolism from blood tests which could lead to kidney failure, heart failure and death.

**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 for advice before you are given this medicine. Noradrenaline (Norepinephrine) Kabi may harm the unborn baby. It is not known whether this medicine is excreted in human milk. Your doctor will decide if you should be given Noradrenaline (Norepinephrine) Kabi.

**Driving and using machines**

You should not drive or use machinery if you are affected by the administration Noradrenaline (Norepinephrine) Kabi.

**Noradrenaline (Norepinephrine) Kabi contains sodium**

This medicinal product contains 3.4 mg sodium (main component of cooking/ table salt) in each ml. This is equivalent to 0.17% of the recommended maximum daily dietary intake of sodium for an adult.

**3. How Noradrenaline (Norepinephrine) Kabi is given**

Noradrenaline (Norepinephrine) Kabi 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 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

**The following information is intended for healthcare professionals only:**

For intravenous use only after dilution. The infusion should be at a controlled rate using either a syringe pump or an infusion pump or a drip counter.

Noradrenaline (Norepinephrine) Kabi should be administered as a diluted solution and it should be administered via a central venous catheter.

If not using a central venous catheter, whenever possible, noradrenaline infusion should be administered into a large vein, particularly an antecubital vein, to minimize the risk of ischemic necrosis (skin, extremities).

A catheter tie-in technique should be avoided if possible, since the obstruction to blood flow around the tubing may cause stasis and increased local concentration of the drug.

**Incompatibilities**

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

**Dilution instructions**

Either add 2 ml concentrate to 48 ml diluent for administration by syringe pump or add 20 ml of concentrate to 480 ml diluent 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 following diluents can be used: sodium chloride 9 mg/ml (0.9% w/v) with glucose 50 mg/ml (5% w/v) infusion glucose 50 mg/ml (5% w/v) infusion sodium chloride 9 mg/ml (0.9% w/v) infusion

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

**Shelf life after opening the ampoule:**

Medicinal product must be used immediately after first opening.

**Shelf life after dilution**

Chemical and physical in-use stability has been demonstrated for 24 hours at 25 °C. From a microbiological point of view, the

accordingly.

**If you are given more Noradrenaline (Norepinephrine) Kabi 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, bleeding in the brain, light sensitivity, pain in the chest, pale colour, high fever, intense sweating, vomiting and fluid in the lungs causing breathlessness.

If you have any further questions on the use of this product, ask your doctor or nurse.

#### 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The frequency of the listed side effects is not known (frequency cannot be estimated from the available data).

**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:**

- anxiety, insomnia, confusion, weakness, psychotic state
- headaches, tremor
- increase of the pressure in your eye (acute glaucoma)
- decreased or increased heart rate
- abnormal heart rhythm
- electrocardiogram change
- a potentially life-threatening type of circulatory failure called 'cardiogenic shock'
- heart muscle weakness due to intense physical or emotional stress, palpitations, increase in the contractility of the heart muscle, acute heart failure
- high blood pressure, decrease in oxygen supply to some organ (hypoxia)
- poor blood flow to your hands and feet (may cause coldness, paleness and/or pain in the limbs)
- gangrene (tissue death)
- reduction in blood plasma volume
- breathing difficulties
- nausea, vomiting
- paleness, scarification of the skin, bluish skin colour, hot flushes or skin redness, skin rash, hives or itching
- retention of urine
- irritation and necrosis (cell injury, causing death of cells in the tissue) at the injection site

Your doctor will monitor your blood pressure and blood volume.

#### Reporting of side effects

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via the national reporting system.

For UK: 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

For Ireland: HPRA Pharmacovigilance  
Website: [www.hpra.ie](http://www.hpra.ie)

By reporting side effects you can help provide more information on the safety of this medicine.

#### 5. How to store Noradrenaline (Norepinephrine) Kabi

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

Do not store above 25 °C. Keep the ampoule in the outer carton in order to protect from light.

Do not use this medicine if you notice it has a brown colour or it contains visible particles.

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

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) Kabi contains

- The active substance is noradrenaline (norepinephrine).  
Each 1 ml concentrate for solution for infusion contains 1 mg noradrenaline base equivalent to 2 mg noradrenaline tartrate. Each ampoule containing 1 ml concentrate for solution for infusion contains 1 mg noradrenaline base equivalent to 2 mg noradrenaline tartrate. Each ampoule containing 4 ml concentrate for solution for infusion contains 4 mg noradrenaline base equivalent to 8 mg noradrenaline tartrate. Each ampoule containing 5 ml concentrate for solution for infusion contains 5 mg noradrenaline base equivalent to 10 mg noradrenaline tartrate. Each ampoule containing 8 ml concentrate for solution for infusion contains 8 mg noradrenaline base equivalent to 16 mg noradrenaline tartrate. Each ampoule containing 10 ml concentrate for solution for infusion contains 10 mg noradrenaline base equivalent to 20 mg noradrenaline tartrate.
- The other ingredients are: sodium chloride, sodium hydroxide (for pH adjustment), hydrochloric acid (for pH adjustment), water for injections.

##### What Noradrenaline (Norepinephrine) Kabi 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 to pale yellow solution.

Clear glass ampoules containing:  
1 ml of concentrate (in pack sizes of 5, 10 or 50); 4 ml, 5 ml, 8 ml and 10 ml of concentrate (each in pack sizes of 5 or 10).

Not all pack sizes may be marketed.

##### Marketing Authorisation Holder and Manufacturer

**Marketing authorisation holder**  
Fresenius Kabi Deutschland GmbH  
Else-Kröner-Straße 1,  
61352 Bad Homburg v.d.Höhe  
Germany

**Manufacturer**  
Labesfal - Laboratórios Almiro, S.A  
Zona Industrial do Lagedo  
3465-157 Santiago de Besteiros  
Portugal

**This leaflet was last revised in March 2021**

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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.

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- if you have low blood pressure that has been caused by low blood volume.
- if you are given the anaesthetic gases halothane or cyclopropane as this may increase the risk of irregular heartbeat.

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- antihistamines (for treating allergies, e.g. chlorpheniramine hydrochloride, triproleamine hydrochloride)
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- maandol (to treat obesity)
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The following diluents can be used:  
sodium chloride 9 mg/ml (0.9% w/v) with glucose 50 mg/ml (5% w/v) infusion  
glucose 50 mg/ml (5% w/v) infusion  
sodium chloride 9 mg/ml (0.9% w/v) infusion

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

- lithium (to treat some mental disorders)
- vasopressin, desmopressin (antidiuretics, to reduce urine production)

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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, bleeding in the brain, light sensitivity, pain in the chest, pale colour, high fever, intense sweating, vomiting and fluid in the lungs causing breathlessness.

If you have any further questions on the use of this product, ask your doctor or nurse.

**4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The frequency of the listed side effects is not known (frequency cannot be estimated from the available data).

**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:**

- anxiety, insomnia, confusion, weakness, psychotic state
- headaches, tremor
- increase of the pressure in your eye (acute glaucoma)
- decreased or increased heart rate
- abnormal heart rhythm
- electrocardiogram change
- a potentially life-threatening type of circulatory failure called "cardiogenic shock"
- heart muscle weakness due to intense physical or emotional stress, palpitations, increase in the contractility of the heart muscle, acute heart failure
- high blood pressure, decrease in oxygen supply to some organ (hypoxia)
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**Reporting of side effects**

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system.

For UK: 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

For Ireland: HPRA Pharmacovigilance  
Website: [www.hpra.ie](http://www.hpra.ie)

By reporting side effects you can help provide more information on the safety of this medicine.

**Shelf life after opening the ampoule:**

Medicinal product must be used immediately after first opening.

**Shelf life after dilution**

Chemical and physical in-use stability has been demonstrated for 24 hours at 25 °C. 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.

#### 5. How to store Noradrenaline (Norepinephrine) Kabi

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

Do not store above 25 °C. Keep the ampoule in the outer carton in order to protect from light.

Do not use this medicine if you notice it has a brown colour or it contains visible particles.

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

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#### 6. Contents of the pack and other information

##### What Noradrenaline (Norepinephrine) Kabi contains

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