

LEAFLET INFORMATION FOR THE USER

NORAGES 1 mg/mL solution for injection

L-Norepinephrine base

Read all 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.
- This medicine has been prescribed for you only. Do not pass it on to others; it may harm them, even if their symptoms 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.

Content of this leaflet:

1. What Norages is and what it is used for
2. What you need to know before you start taking NORAGES
3. How to use Norages
4. Possible side effects
5. How to store Norages
6. Contents of the pack and other information

1. What Norages is and what it is used for

Norages belongs to the group of medicines called "adrenergic and dopaminergic" agents which act increasing blood pressure.

Norages is used to treat acute hypotension (decreased blood pressure)

2. What you need to know before you start taking Norages

Do not use Norages:

- If you are allergic (hypersensitive) to L-norepinephrine bitartrate monohydrate or to any of the other ingredients of this medicine.
- If during anesthesia you are going to be administered other medicines such as halothane or cyclopropane.
- If you have gastrointestinal ulcers or bleeding.

Be particularly careful if:

- You are a diabetic patient
- You had hyperthyroidism
- If your oxygenation status is insufficient
- If you have any occlusive (obstructive) disease such as arteriosclerosis (hardening of the arteries), Buerger's disease (inflammation of a vein with thrombus formation), diabetes mellitus.
- You have had thrombosis

Warnings and precautions

Talk to your doctor or pharmacist before you start taking this medicinal product.

Other medicines and Norages

Tell your doctor or pharmacist if you are using, have recently used, or might use any other medicines. Certain medicines may interact with Norages, and it may be necessary to change the dosage of Norages and/or such medicines and administer them with caution. It is important to tell your doctor or pharmacist if you are using, have recently used, any of the following medicines:

- Organic Anaesthetics
- Tricyclic antidepressants (used to treat depression) or maprotiline
- Digitalis glycosides (heart medications)
- Ergoloid mesylates or ergotamine (headache medications)
- Levodopa (medicinal product to treat Parkinson's disease)
- Cocaine
- Guanadrel and guanetidine (medicinal products to treat high blood pressure)
- Hydrochloric chlorpheniramine, hydrochloric triphenylamine (medicinal products used to treat allergy), and desipramine (medicinal products used to treat depression)
- Antihistamines (medicines to treat allergies).
- Amphetamines (central nervous system stimulating Medicinal product)
- Dihydroergotamine (headache medication) ergometrine, methylergometrine (medication for the treatment of post-partum hemorrhage or abortion), or methysergide (headache medication)
- Doxapram (respiratory stimulant medication)
- Mazindol (medication to treat obesity)
- Mecamylamine (medicine to stop smoking) or

methyl dopa (high blood pressure medicine)

- Methylphenylate (central nervous system stimulating medicinal product)
- Alkaloids from rauwolfia (medicinal product used for high blood pressure)
- Other sympathomimetics (medications that increase blood pressure)
- Thyroid hormones (treatment of metabolic problems)
- Monoamine oxidase inhibitors (MAOIs) (medicinal product used to treat depression)
- Medicinal products to treat tension or to increase urination (diuretics)
- Beta-adrenergic blockers (medicinal products used to treat high blood pressure)
- Desmopressin (medicinal product used for uncontrolled nighttime urine leakage), lysopressin, or vasopressin (medicinal products used to treat hypotension and anti-diuretics)
- Lithium (medicinal product for the treatment of mental illness)

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, as there may be risks to the unborn child.

It is not known whether Norages is excreted in breast milk so your doctor will assess the need for administration.

Norages 1 mg/mL contains sodium.

This medicine contains less than 23 mg (1 mmol) of sodium per 4-mL ampoule; therefore, it is essentially considered "sodium-free".

3. How to use Norages

Always use Norages 1 mg/mL exactly as described in this leaflet or as your doctor has told you. Any doubts regarding the use of this product, ask your doctor again.

Norages 1 mg/mL, is administered intravenously by a healthcare professional.

Adults

The initial dose is administered at a rate of 8 to 12 micrograms (0,008 to 0,012 mg) (base) per minute. For maintenance, the speed is adjusted from 2 to 4 micrograms (0,002 to 0,004 mg) (base) per minute.

For septic shock, doses should be adjusted approximately to 0.5 micrograms per kg and per minute (up to a maximum of 1.0 micrograms per kg, per minute).

Children

Intravenous infusion, 0.1 micrograms (base) per kg, per minute. Up to a maximum of 1 microgram (base) per kg, per minute.

If you use more Norages than you should:

A severe rise in tension may occur with severe headache, light rejection, sharp pain behind the breastbone (in the chest), pain in the pharynx, severe paleness and sweating, and vomiting. In case of overdose or accidental ingestion, consult the Toxicology Information Service. Phone: 91 – 5620420.

4. Possible side effects

Like all medicines, Norages can cause side effects, though not everybody gets them. If fluid leaks out of the vein, surrounding tissue may be destroyed.

Heart rate reduction may occur.

Prolonged use may decrease heart output. Prolonged administration of this type of substance can lead to loss of blood fluids which, if not corrected, can cause a relapse into a drop in blood pressure when treatment is stopped. Severe narrowing of the body's veins and viscera (e.g. decreased blood supply to the kidney) can occur with decreased blood flow and tissue irrigation, resulting in lack of oxygen to the tissues, increased blood acidity, and damage due to lack of blood supply. Although rare, the following symptoms requiring medical attention may occur during application:

Skin disorders: Paleness of the skin along the infusion vein, scarification, bluish discoloration, hot flashes or redness of the skin, skin rash, hives, or itching.

Disorders of the cardiovascular system:

Irregular heartbeat, decreased heart rate.

Respiratory system disorders: Wheezing or breathing difficulty

General disorders: Severe dizziness or feeling faint.

Less common, the following symptoms may occur and require medical attention only if they last or are bothersome:

Skin disorders: Pallor.

Disorders of the cardiovascular system: Heart palpitations.

Nervous system disorders: Anxiety or restlessness, sleep problems, tremors, headaches.

General disorders: Dizziness, swelling in the neck.

In sensitive people, for example people with nervous or hyperthyroid diseases, it produces:

Nervous disorders: fear, anxiety, pulsating headache and shortness of breath.

Disorders of the cardiovascular system: paleness, tachycardia, palpitations, (discreet) elevation of blood pressure.

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

5. How to store Norages

Keep this medicine out of the sight and reach of children. Do not use this medicine after the expiration date which is stated on the carton after EXP. Expiry date is the last day of that month. Do not store at temperatures higher than 25°C. Store in the original container to protect from light. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away packages and medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Norages contains

- The active substance is norepinephrine (L-norepinephrine) base. Each mL of solution contains 1 mg of norepinephrine (L-norepinephrine) base equivalent to 2 mg of bitartrate of norepinephrine (L-norepinephrine) monohydrate
- The other ingredients (excipients) are sodium chloride and water for injections.

What Norages looks like and contents of the pack

Norages 1 mg/mL is a solution for injection presented in packages of 10, 4 mL-ampoules.

Marketing Authorisation Holder and Manufacturer

Altan Pharmaceuticals, S.A.
C/ Cólquide N°6, Portal 2, 1ª Planta, Oficina F
Edificio Prisma
Las Rozas, 28231 Madrid. Spain

Manufacturer responsible:

Laboratorio RENAUDIN
Z.A. Errobi
64250 Itxassou, France

This leaflet has been approved in June 2026

Detailed and updated information of this medicinal product is available at the Web site of the Spanish Agency for Medicines and Medicinal Products (AEMPS, Spanish Acronym for Agencia Española de Medicamentos y Productos Sanitarios (AEMPS) <http://www.aemps.gob.es>

This information is only intended for physicians or healthcare professionals:

Posology and method of administration

Norepinephrine must be administered intravenously:

Usual posology for adults

The initial dose is administered at a rate of 8 to 12 micrograms (0.008 to 0.012 mg) (base) per minute, with the rate of administration adjusted so as to establish and maintain the desired blood pressure. For maintenance, the speed is set from 2 to 4 micrograms (0.002 to 0.004 mg) (base) per minute, titrated according to patient response. For septic shock, doses should be adjusted

approximately to 0.5 microgram/kg/min (up to a maximum of 1.0 microgram/kg/min) to achieve the desired mean blood pressure. It is recommended to be administered together with 2 - 2.5 micrograms/kg/min doses of dopamine, which counteract vasoconstriction, thus ensuring good renal and splanchnic circulation.
- To prepare the solution for intravenous norepinephrine infusion, add 4 mg of L-norepinephrine (base) to 1 liter of 5% glucose solution. The resulting solution will contain 4 micrograms (0.004 mg) of L-norepinephrine (base) per mL. It should be noted that 1 mg of L-norepinephrine bitartrate equals 0.5 mg of L-norepinephrine base.

Duration of treatment

Infusion should be continued until adequate blood pressure and tissue perfusion are maintained without treatment. Norepinephrine infusion should be gradually reduced, avoiding sudden interruption. In some documented cases of vascular collapse due to acute myocardial infarction, treatment was required for up to six days.

Usual Paediatric Posology

Intravenous infusion, 0.1 micrograms (base) per kg per minute, gradually adjusting the delivery rate to achieve the desired blood pressure, up to 1 microgram (base) per kg, per minute.
- When added to local anesthetics, these solutions contain approximately 1-norepinephrine concentration: 200,000 (5 micrograms/mL).

Do not use Norages if:

- Norepinephrine should not be used as sole therapy in hypotensive patients due to hypovolaemia except as an emergency measure to maintain coronary and cerebral artery perfusion until completion of volume replacement therapy.
- Its administration into the veins of the lower limbs in elderly and patients with occlusive diseases due to possible vasoconstriction should be avoided.
- There may be accidental cases in which failure to take the proper precautions can lead to extravasation or even gangrene. To prevent necrosis and tissue scarification in areas where extravasation has occurred, the site should be infiltrated immediately with 10 to 15 mL of sodium chloride containing 5 to 10 mg of phentolamine. A syringe with a fine hypodermic needle should be used and the solution should be infiltrated abundantly through the entire area. If the area is infiltrated within 12 hours, the sympathetic blockage with phentolamine produces immediate and noticeable local hyperemic changes.
- The volume of blood lost should be replaced as completely as possible before administering any vasopressor.

Special Usage Precautions

- Before administration, norepinephrine for injection should be diluted with 5% glucose in distilled water or 5% glucose in sodium chloride solution. Do not use sodium chloride solution alone.
- To prepare the solution for intravenous norepinephrine infusion, add 4 mg of L-norepinephrine (base) to 1 liter of 5% glucose solution. The resulting solution will contain 4 micrograms (0.004 mg) of L-norepinephrine (base) per mL. It should be noted that 1 mg of L-norepinephrine bitartrate equals 0.5 mg of L-norepinephrine base.
- Use a controlled drip system to get an accurate estimate of the flow rate in drops per minute. The infusion must be made into veins of the upper extremities.
- Ligation catheter technique should be avoided, if possible, because obstruction of blood flow around the tube may result in stasis and increased local norepinephrine concentration.
- Do not use the solution for injection if it is brown or contains a precipitate.

Overdosage

Symptoms

Overdose causes severe hypertension with severe headache, photophobia, acute retrosternal pain, pharyngeal pain, severe paleness and sweating, and vomiting.

Emergency treatment, antidotes

Recommended treatment for norepinephrine overdose includes:

- discontinuation of medicinal product
- adequate fluid and electrolyte replacement therapy

for hypertensive effects: if necessary, adrenergic blocker can be given directly intravenously with 5 to 10 milligrams of phentolamine.

FORMATO:

- 148 x 315 mm.

TIPO Y TAMAÑO DE LETRA:

- **Titular:** Helvética Bold, 10 puntos (compresión 95%).
- **Cuerpo de texto:** Helvética regular y bold, 9 puntos (compresión 90%).
- **Interlineado:** 9 puntos

Código: LFTNORAIR-00