# NORADRENALINE (TARTRATE) AGUETTANT 2 mg/ml (SULFITES FREE), 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.

**In this leaflet:**



## 1. WHAT NORADRENALINE (TARTRATE) AGUETTANT 2 mg/ml (SULFITES FREE), concentrate for solution for infusion IS, AND WHAT IT IS USED FOR

Pharmacotherapeutic class: CARDIAC STIMULANTS EXCLUDE CARDIAC GLYCOSIDES

ATC Code: C01CA03.

This medicine is used as the emergency treatment of collapse and in the restoration and keeping of blood pressure.

In the local gastric irrigation, noradrenaline is used in the treatment of digestive haemorrhages, in addition to the usual treatments.

## 2. WHAT YOU NEED TO KNOW BEFORE YOU USE NORADRENALINE (TARTRATE) AGUETTANT 2 mg/ml (SULFITES FREE), concentrate for solution for infusion

**Never use NORADRENALINE (TARTRATE) AGUETTANT 2 mg/ml (SULFITES FREE), concentrate for solution for infusion:**
- if you are allergic to preparations containing noradrenaline or any of the other ingredients of this medicine (listed in section 6).

**Warnings and precautions**

Talk to your doctor, pharmacist, or nurse before using NORADRENALINE (TARTRATE) AGUETTANT 2 mg/ml (SULFITES FREE), concentrate for solution for infusion.

**Special warnings**

NORADRENALINE (TARTRATE) AGUETTANT 2 mg/ml (SULFITES FREE), concentrate for solution for infusion is contraindicated in hypotensive patients in whom circulatory collapse is associated with hypovolaemia (decrease of effective blood volume) except as an emergency measure to maintain supply to the coronary and cerebral arteries until blood volume replacement therapy can be instituted.

*Risk of extravasation:*

Your doctor will check the infusion site to take precautions to avoid spread of liquid into the surrounding tissue.

**Special precautions for use**

NORADRENALINE (TARTRATE) AGUETTANT 2 mg/ml (SULFITES FREE), should be used with caution and in strict respect of the indication in case of:
- major left ventricular dysfunction
- acute coronary insufficiency (angina pectoris)
- recent myocardial infarction (heart attack)
- heart rhythm disorders arriving during the treatment. The latter must lead to a reduction in the dosage.

Inform your doctor if you are suffering from hyperthyroidism or diabetes mellitus.

The blood pressure and heart rate should be checked continuously during an infusion of noradrenaline.

If it is necessary to administer NORADRENALINE (TARTRATE) AGUETTANT 2 mg/ml (SULFITES FREE), concentrate for solution for infusion simultaneously with total blood or blood plasma, these latter must be administered separately.

**Other medicines and NORADRENALINE (TARTRATE) AGUETTANT 2 mg/ml (SULFITES FREE), concentrate for solution for infusion**

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Use of NORADRENALINE (TARTRATE) AGUETTANT 2 mg/ml (SULFITES FREE), concentrate for solution for infusion, is inadvisable in combination with:
- Anaesthetics (specially anaesthetic gas),
- Antidepressants (imipramine, serotoninergic-noradrenergic).

You should notify your doctor if you have taken the following drugs:
- Selective and non selective MAO inhibitors
- Linezolid (an antibiotic)
- Methylene blue

**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 using this medicine.

Considering the indications, use of noradrenaline can be envisaged during pregnancy if necessary. Nevertheless, take into account the pharmacological properties of the product.

Indeed, noradrenaline may impair placental perfusion and induce fetal bradycardia.

It may also exert a contractile effect on the pregnant uterus and lead to fetal asphyxia in late pregnancy.

No information is available on the use of noradrenaline in breast-feeding.

**NORADRENALINE (TARTRATE) AGUETTANT 2 mg/ml (SULFITES FREE), concentrate for solution for infusion 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 TO USE NORADRENALINE (TARTRATE) AGUETTANT 2 mg/ml (SULFITES FREE), concentrate for solution for infusion

**Posology**

Doses must be adapted according to the clinical state of the patient. Initial recommended doses are 0.1 to 0.3 µg/kg/min of noradrenaline tartrate.

Doses reaching 3 to 5 µg/kg/min were sometimes useful in the treatment of the septic shock or haemorrhagic shock. Once the infusion started, the dose of noradrenaline tartrate should be titrated by increments according to the effect observed on the mean blood pressure.

The infusion must be controlled using an electric syringe driver or a volumetric pump. The infusion speed must be calculated using the following formula:

$$\text{Rate (ml/h)} = \frac{\text{Dose (µg/kg/min) x Weight (kg) x 60 min}}{\text{Dilution (mg/ml) x 1000}}$$

In digestive haemorrhage case, 8 to 16 mg of noradrenaline added to frozen physiological serum could be used for gastric washing.

**Route of administration**

Intravenous route only. You should strictly follow the medical prescription.

The route of administration must be necessarily the intravenous route. Each extravasion can induce an intense local vasoconstriction and possible tissue necrosis. It is preferable to use a central venous route.

NORADRENALINE (TARTRATE) AGUETTANT 2 mg/ml (SULFITES FREE), concentrate for solution for infusion must be diluted prior to intravenous infusion, as a rule, in an isotonic glucose solution or isotonic sodium chloride. Noradrenaline should not be mixed with other medicines.

**Instructions for opening the ampoules**

At the base of the neck of the ampoule is a thin break point indicated by a coloured spot.

Hold the ampoule with the coloured spot facing towards you. The ampoule can be opened easily by placing the thumb on the coloured spot and pressing downwards, as shown in the illustration.

**If you have used more NORADRENALINE (TARTRATE) AGUETTANT 2 mg/ml (SULFITES FREE), concentrate for solution for infusion than you should:**

Consult your doctor or pharmacist immediately.

In the event of overdose, the following may be observed: cutaneous vasoconstriction (narrowing of blood vessels), pressure sores, circulatory collapse and hypertension.

In the event of adverse reactions linked to an excessive dosage, contact your doctor immediately. He will take the appropriate measures.

It is recommended to reduce the dosage if possible.

## 4. POSSIBLE SIDE EFFECTS

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

Vascular disorders: high blood pressure, and decrease in oxygen supply to some organs, coldness and paleness of the members and the face.

Cardiac disorders: fast or slow heart rate, irregular heart beats, palpitations, increase in the contractility of the cardiac muscle, acute cardiac insufficiency.

Nervous system disorders: anxiety, headache, tremor, and vomiting.

Renal and Urinary disorders: retention of urine.

Respiratory disorders: Respiratory insufficiency or difficulty, dyspnea (breathing difficulties).

Locally: possibility of irritation and necrosis (cell injury, causing death of cells in the tissue) at the injection site.

Eyes disorders: Acute glaucoma.

The continuous administration of vasopressor to maintain blood pressure in the absence of blood volume replacement may cause the following symptoms:

- severe peripheral and visceral vasoconstriction,
- decrease in renal blood flow,
- decrease in urine production,
- hypoxia,
- increase in lactate serum levels.

In case of hypersensitivity or overdose, the following effects may appear more frequently: arterial hypertension (high blood pressure), photophobia (abnormal intolerance to visual perception of light), retrosternal pain (thoracic pain), pharyngeal pain (throat pain), pallor, intense sweating and vomiting.

**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:

**France:** Agence nationale de sécurité du médicament et des produits de santé (ANSM) et réseau des Centres Régionaux de Pharmacovigilance - Website: www.signalement-sante.gouv.fr.

**Malta:** ADR Reporting - Website: www.medicinesauthority.gov.mt/adrportal

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

## 5. HOW TO STORE NORADRENALINE (TARTRATE) AGUETTANT 2 mg/ml (SULFITES FREE), concentrate for solution for infusion

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 ampoule. The expiry date refers to the last day of that month.

Before dilution: Store below 25°C. Store in the outer packaging protected from light.

After dilution: The physicochemical stability of the product following dilution (in glucose 5% or sodium chloride 0.9%) has been demonstrated for 48 hours at 25°C. However, in terms of microbiological purity, the product must be used immediately. If it is not used immediately, the duration and conditions of storage are the sole responsibility of the user and should not normally exceed 12 hours at 25°C in a plastic syringe for an electric syringe driver.

This product should be visually inspected prior to administration. Only a clear slightly yellow solution, free of particles or precipitates should be used. Do not use ampoules with a pink color or darker than pale yellow, or containing a precipitate.

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 (TARTRATE) AGUETTANT 2 mg/ml (SULFITES FREE), concentrate for solution for infusion contains**

**The active substance is:**

Noradrenaline tartrate ..... 2 mg

For 1 ml of solution for injection.

Or 8 mg of noradrenaline tartrate (corresponding to 4 mg of noradrenaline base) for one 4 ml ampoule.

Or 16 mg of noradrenaline tartrate (corresponding to 8 mg of noradrenaline base) for one 8 ml ampoule.

**The other ingredients are:**

Sodium chloride, sodium hydroxide or hydrochloric acid (qs pH = 3.0 to 4.0), water for injections.

**What NORADRENALINE (TARTRATE) AGUETTANT 2 mg/ml (SULFITES FREE), concentrate for solution for infusion looks like and content of the pack**

This medicine is supplied in the form of concentrate for solution for injection in 4 ml or 8 ml ampoules. Boxes of 10, 50 or 100.

**Marketing Autorisation Holder / Distributor**

Laboratoire AGUETTANT
1, rue Alexander Fleming
69007 LYON
France

**Manufacturers**

Laboratoire AGUETTANT
1 rue Alexander Fleming
69007 LYON
France
Or
DELPHARM Tours
Rue Paul Langevin
37170 CHAMBRAY-LES-TOURS
France

**This leaflet was last revised in 03/2019.**

**France:** Detailed information on this medicine is available on the ANSM (France) website.

**Malta:** Detailed information on this medicine is available on the Medicines Authority website (Malta).