

PACKAGE LEAFLET: INFORMATION FOR THE USER

SINORA 0.1 mg/ml solution for infusion

SINORA 0.2 mg/ml solution for infusion

noradrenaline

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 or nurse.
- 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 SINORA is and what it is used for
2. What you need to know before you are given SINORA
3. How to use SINORA
4. Possible side effects
5. How to store SINORA
6. Contents of the pack and other information

1. What SINORA is and what it is used for

SINORA contains the active substance noradrenaline and act as a vasoconstrictor.

SINORA is used for the emergency restoration of blood pressure in cases of suddenly decreased blood pressure (acute hypotension).

2. What you need to know before you are given SINORA

Do not use SINORA:

- if you are allergic to noradrenaline or 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 or nurse before using SINORA

- if you have diabetes
- if you suffer from high blood pressure
- if you have an over-active thyroid
- if you have low levels of oxygen in the blood
- if you have high levels of carbon dioxide in the blood
- if you have clots or obstructions in the blood vessels supplying the heart, intestines or other parts of the body
- if you have low blood pressure following a heart attack
- if you have a type of angina (chest pain) called Prinzmetal's angina
- if you are elderly
- if you have extravasation risk (risk that your blood or lymph escape from their proper vessels into surrounding tissues)
- if you have major left ventricular dysfunction
- if you have recently had myocardial infarction (a heart attack)

•if you have cardiac rhythm disorders (your heart beats too fast, too slow or irregular), you will need a reduced dose.

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

Other medicines and SINORA

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

A number of medicines are known to increase the toxic effects of noradrenaline, such as:

- 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 heartbeat.
- Amitriptiline, Imipramine, Trimipramine, Moclobemide, Iproniazide, Phenelzine, 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, 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 for advice before taking this medicine.

Noradrenaline may harm the unborn baby. Your doctor will decide if you should be given SINORA .

Paediatric population

SINORA is indicated for adults only.

The safety and efficacy in children and adolescents have not been established.

Driving and using machines

Since SINORA will be given to you in a hospital, your doctor will inform you when you are able to drive or use machines.

SINORA contains Sodium

This medicine contains 165.3 mg sodium (main component of cooking/table salt) in each 50 ml vial. This is equivalent to 8.3% of the recommended maximum daily dietary intake of sodium for an adult.

3. How to use SINORA

SINORA will be used to you in the hospital by a doctor or nurse.

If you have been given too much SINORA

It is unlikely that you will receive too much as this medicine will be given to you in the 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.

If you have any further questions on the use of this medicine, 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 adverse reactions cannot be estimated from the available data.

Tell your doctor as soon as possible if you experience:

- slow heart rate, fast heart rate, palpitations, increase in the contractility of the cardiac muscle, acute cardiac insufficiency
- abnormal heart rhythm
- breathing difficulties
- anxiety, insomnia, confusion, weakness, psychotic state
- headaches, tremor
- high blood pressure (arterial hypertension), decrease in oxygen supply to some organ (hypoxia)
- acute glaucoma
- cold extremities
- pain in the extremities
- nausea, vomiting
- retention of urine
- locally: possibility of irritation and necrosis (cell injury, causing death of cells in the tissue) at the injection site.

In case of hypersensitivity or overdose, the following effects may appear more frequently: 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.

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
HPRA Pharmacovigilance

Website: www.hpra.ie

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

5. How to store SINORA

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 carton and vial label after EXP.

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

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

This medicine should not be used if the solution is darker than slightly yellow or pink in colour or if it contains a precipitate.

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

6. Contents of the pack and other information

What SINORA contains

The active substance is noradrenaline (as noradrenaline tartrate).

Sinora 0.1 mg/ml

1 ml of solution for infusion contains 0.2 mg noradrenaline (norepinephrine) tartrate equivalent to 0.1 mg noradrenaline (norepinephrine) base.

Sinora 0.2 mg/ml

1 ml of solution for infusion contains 0.4 mg noradrenaline (norepinephrine) tartrate equivalent to 0.2 mg noradrenaline (norepinephrine) base.

The other ingredients are Sodium Chloride, Hydrochloric acid 1 N (for pH-adjustment), Water for injections.

What SINORA looks like and contents of the pack

This medicinal product is presented as solution for infusion. The solution is clear colourless solution.

The medicinal product is available in packs containing 1 vial of solution for infusion.

Marketing Authorisation Holder:

Sintetica GmbH
Albersloher Weg, 11
48155 – Münster
Germany

Manufacturer:

Sirton Pharmaceuticals Spa
Piazza XX Settembre, 2
22079 Villa Guardia (CO)
Italy

or

Sintetica GmbH
Albersloher Weg 11
48155 Münster
Germany

This leaflet was last revised in**The following information is intended for healthcare professionals only:**

For intravenous use.

Not dilute before use: it is supplied ready to use. SINORA solution for infusion is infused intravenously. To avoid ischemic necrosis (skin, extremities) a cannula placed in a sufficiently larger vein or a central venous access to the infusion should be used.

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 tartrate 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.

Special precautions for disposal and other handling

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