PACKAGE LEAFLET: INFORMATION FOR THE USER

SINORA
1 mg/ml Concentrate for solution for infusion
Noradrenaline (as noradrenaline tartrate)

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 pharmacist.
- 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 pharmacist. 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

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 SINORA is given to you

Do not use SINORA:
- if you are allergic (hypersensitive) to noradrenaline preparations 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 or pharmacist 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 (a heart condition)
• 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
Please tell your doctor or nurse if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

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 or nurse for advice before taking any medicine.
Noradrenaline may harm the unborn baby. Your doctor will decide if you should be given SINORA 1 mg/ml Concentrate for solution for infusion.

Paediatric population
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 will be able to drive or use machines.

SINORA contains Sodium
This medicinal product contains less than1 mmol sodium (23 mg) per 1 ml, 4 ml and 5 ml ampoule, that is to say essentially ‘sodium free’.
This medicine contains 33 mg sodium (main component of cooking/table salt) in each 10 ml ampoule. This is equivalent to 1.7% of the recommended maximum daily dietary intake of sodium for an adult.

3. How to use SINORA

SINORA will be used to you in 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 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 product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, SINORA 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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via

HPRA Pharmacovigilance
Earlsfort Terrace
IRL – Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
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 SINORA after the expiry date {month/year} which is stated on the outer carton and on the ampoule.
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.
From a microbiological point of view, the product should be used immediately after dilution.
Do not throw away any medicines via wastewater. 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 SINORA contains

The active substance is noradrenaline (as noradrenaline tartrate).
1 ml concentrate for solution for infusion contains 2 mg noradrenaline tartrate equivalent to 1 mg noradrenaline base.

The other ingredients are sodium chloride and water for injections.

What SINORA looks like and contents of the pack

This medicinal product is presented as a concentrate for solution for infusion. The solution is clear colourless solution.
The medicinal product is available in packs containing 10 ampoules x 1 ml, 10 ampoules x 4 ml, 10 ampoules x 5 ml, 10 ampoules x 10 ml of concentrate for solution for infusion.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Sintetica GmbH
Albersloher Weg, 11
48155 – Münster
Germany

Manufactured by:

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

or

Sintetica GmbH
Albersloher Weg 11
48155 Münster
Germany

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

DE	Noradrenaline Sintetica 1 mg/ml Konzentrat zur Herstellung einer Infusionslösung
BG	Sinora 1 mg/ml Концентрат за инфузионен разтвор
EE	Norepinephrine Sintetica
EL	Sinora 1 mg/ml Πυκνό διάλυμα για παρασκευή διαλύματος προς έγχυση
FI	Noradrenaline Sintetica 1 mg/ml Infuusiokonsentraatti, liuosta varten
HR	Sinora 1 mg/ml Koncentrat za otopinu za infuziju
IE	Sinora 1 mg/ml Concentrate for solution for infusion
IS	Noradrenalin Sintetica 1 mg/ml Innrennslisþykkni, lausn

LV	Sinora 1 mg/ml Koncentrāts infūziju šķīduma pagatavošanai
LT	Norepinephrine Sintetica 1 mg/ml koncentratas infuziniam tirpalui
NL	Sinora 1 mg/ml concentraat voor oplossing voor infusie
NO	Noradrenalin Sintetica
SE	Noradrenaline Sintetica 1 mg/ml koncentrat till infusionsvätska, lösning
SI	Noradrenalin Sintetica 1 mg/ml koncentrat za raztopino za infundiranje

This leaflet was last revised in August 2022

The following information is intended for medical or healthcare professionals only:

For intravenous use.
Dilute before use.
SINORA solution for infusion is infused as a diluted solution 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.

Dilution instructions
Dilute before use with glucose 5% solution or sodium chloride 9 mg/ml (0.9%) or sodium chloride 9 mg/ml with glucose 5 % solution.
Either add 2 ml concentrate to 48 ml glucose 5% solution (or sodium chloride 9 mg/ml or sodium chloride 9 mg/ml with glucose 5% solution) for administration by syringe pump, or add 20 ml of concentrate to 480 ml glucose 5 % solution (or sodium chloride 9 mg/ml or sodium chloride 9 mg/ml with glucose 5% solution) 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 product is compatible with PVC infusion bags.
Any unused product or waste material should be disposed of in accordance with local requirements.

Shelf life after dilution
Chemical and physical in-use stability has been demonstrated for 24 hours at 25°C when diluted to 4 mg/litre and 40 mg/litre noradrenaline base in sodium chloride 9 mg/ml (0.9%) solution or glucose 5% solution or sodium chloride 9 mg/ml with glucose 5% solution. However, 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