

## **PACKAGE LEAFLET: INFORMATION FOR THE USER**

Sinora

0.08 mg/ml solution for infusion

0.16 mg/ml 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, 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.

### **What is in this leaflet:**

1. What Sinora is and what it is used for
2. What you need to know before Sinora is given to you
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 is a medicine that belongs to the group of adrenergic and dopaminergic agents.

Sinora is indicated in adults weighing over 50 kg for the on-going treatment of hypotensive emergencies with escalating noradrenaline dose requirements.

The product is for adults only.

### **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).

## **Warnings and precautions**

### **Talk to your doctor, pharmacist 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).*

## **Children and adolescents**

Sinora 0.08 mg/ml solution for infusion and Sinora 0.16 mg/ml solution for infusion is indicated for adults only.

## **Other medicines and Sinora**

Tell your doctor, pharmacist 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:

- monoamine oxidase inhibitors (antidepressants)
- tricyclic antidepressants
- linezolid (an antibiotic)
- anaesthetics (especially anaesthetic gases)
- adrenergic-serotonergic medicines, e.g. used in the treatment of asthma and heart conditions.

## **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..

### **Driving and using machines**

None stated.

### **Important information about some of the ingredients of Sinora**

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 hospital by a doctor or nurse. The dose of Sinora solution for infusion will depend on your condition. Your doctor will know the best dose to use.

#### **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 medicine, ask your doctor, pharmacist 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](http://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 {month/year} which is stated on the outer carton and on the vial. The expiry date refers to the last day of that month.

After the first opening, the product should be used immediately.

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

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).

#### *Sinora 0.08 mg/ml*

Each ml of solution for infusion contains 0.16 mg noradrenaline tartrate equivalent to 0.08 mg noradrenaline base.

Each 50 ml vial contains 8 mg of noradrenaline tartrate equivalent to 4 mg of noradrenaline base.

#### *Sinora 0.16 mg/ml*

Each ml of solution for infusion contains 0.32 mg noradrenaline tartrate corresponding to 0.16 mg noradrenaline base. Each 50 ml vial contains 16 mg of noradrenaline tartrate equivalent to 8 mg of noradrenaline base.



For intravenous use.

Not dilute before use: it is supplied ready to use. Administer via a central venous catheter.

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**

For single use only. Discard any unused contents.

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