PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

SINORA 0,08 mg/ml

SINORA 0,16 mg/ml

Solution for infusion

Noradrenaline (as noradrenaline tartrate)

Read all of this leaflet carefully before you are given SINORA

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other health care provider.

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 you will be given 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, which acts as a vasoconstrictor (narrows blood vessels). SINORA is used for the ongoing treatment of hypotensive (very low

blood pressure) emergencies. SINORA is indicated in adults weighing over 50 kg only.

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

SINORA should not be given to you:

- if you are hypersensitive (allergic) to noradrenaline preparations or to any of the other ingredients of SINORA (listed in section 6).
- if you are hypotensive (have low blood pressure) that has been caused by hypovolaemia (low blood volume).
- if you are going to receive certain anaesthetics, such as halogenated anaesthetics (this may increase the risk of irregular heart beat).

Warnings and precautions

Tell your doctor or healthcare professional before being given SINORA:

- if you suffer from high blood pressure.
- if you have low blood pressure following a heart attack.
- if you have clots or obstructions in the blood vessels supplying the heart, intestines or other parts of the body.
- if you have a type of angina (chest pain) called Prinzmetal's angina.
- if you have diabetes.
- 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 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 SINORA, your doctor will check continuously your blood pressure and cardiac frequency (heart rate).

Children and adolescents

SINORA is indicated for use in adults only. The efficacy and safety of SINORA in children and adolescents has not been established.

Other medicines and SINORA

Always tell your healthcare professional if you are taking any other medicine (This includes complementary or traditional medicines).

Tell your doctor if you are taking/using, have recently taken/used, or might take/use any other medicines:

- Halothane, cyclopropane: these medicines are anaesthetics, which cause insensitivity to pain and are used before some operations. If you receive these medicines as well as SINORA, this may increase the risk of irregular heartbeat.
- Amitriptiline, imipramine, trimipramine, moclobemide, iproniazide, phenelzine, fluoxetine, sertraline: these medicines are used for the treatment of depression. Taking any of these medicines together with SINORA can dangerously increase its concentration in the blood and therefore its ability to increase the blood pressure.
- Linezolid, an antibiotic (used to treat infections caused by bacteria and other microorganisms), can dangerously increase the SINORA concentration in the blood

and therefore its ability to increase the blood pressure, when taken together.

- Alpha and beta-blockers: if you are taking these medicines as well as SINORA, this may increase the risk of severe hypertension (high blood pressure).
- Thyroid hormones (used to treat the thyroid gland), cardiac glycosides (used to treat heart failure and irregular heart beat), antidysrhythmics (medicines used to treat irregular heart beat): if you are taking these medicines as well as SINORA this may cause increased effects on the heart.
- Ergot alkaloids (used for the treatment of migraine) or oxytocin (a hormone) taken together with SINORA may significantly increase the extent to which blood vessels are narrowed and as such significantly increase blood pressure.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before being given this medicine.

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

Driving and using machines

It is not always possible to predict to what extent SINORA may interfere with your daily activities. You should ensure that you do not engage in driving or operating machines until you are aware of the measure to which SINORA affects you.

SINORA contains sodium

SINORA 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.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

3. How SINORA will be given

Do not share medicines prescribed for you with any other person.

You will not be expected to give yourself SINORA. It will be given to you by a person who is qualified to do so.

If you are given more SINORA than you should

Since a health care provider will administer SINORA, he / she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

4. Possible side effects

SINORA can have side effects.

Not all side effects reported for SINORA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking SINORA, please consult your health care provider for advice.

If any of the following happens, stop taking / using SINORA and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Allergic reaction (swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing; rash or itching, fainting).
- 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 (pain occurring behind the breast bone), pharyngeal pain (throat pain), pallor (pale colour of the skin), intense sweating and vomiting.

These are all very serious side effects. If you have them, you may have had a serious reaction to SINORA. You may need urgent medical attention or hospitalisation.

Tell your doctor as soon as possible if you experience:

- slow heart rate, fast heart rate or irregular heart rate.
- high blood pressure (arterial hypertension).
- decrease in oxygen supply to some organs (hypoxia) (the skin colour can turn bluish or grey).
- cold extremities.
- paleness of the skin or extremities.
- breathing difficulties.
- acute glaucoma (increased pressure in the eye).
- feeling anxious or confused.
- psychotic state (hallucinating, hearing voices, not thinking clearly).
- retention of urine (being unable to urinate) decrease in urine production.
- being unable to sleep (insomnia).
- feeling weak.
- headaches.
- tremor (uncontrolled shivering).
- nausea, vomiting.
- pain in the extremities.
- possibility of irritation and necrosis (cell injury, causing death of cells in the tissue) at

the injection site.

Your doctor will monitor your blood pressure and blood volume.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

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

5. How to store SINORA

Store at or below 25 °C.

Do not refrigerate or freeze.

Store in the original package in order to protect from light.

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

Do not use after the expiry date, which is stated on the outer carton and on the vial. The expiry date refers to the last day of that month.

Keep this medicine out of the sight and reach of children.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

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 1 ml contains 0,16 mg noradrenaline tartrate equivalent to 0,08 mg noradrenaline base.
Each 50 ml vial contains 8 mg of noradrenaline tartrate corresponding to 4 mg of noradrenaline base.

SINORA 0,16 mg/ml

Each 1 ml contains 0,32 mg noradrenaline tartrate equivalent to 0,16 mg noradrenaline base.
Each 50 ml vial contains 16 mg of noradrenaline tartrate corresponding to 8 mg of noradrenaline base.

The other ingredients are hydrochloric acid, sodium chloride and water for injections.

What SINORA looks like and contents of the pack

SINORA 0,08 mg/ml and SINORA 0,16 mg/ml are clear, colourless solutions.

SINORA 0,08 mg/ml is presented in Type I clear, colourless glass vials closed with bromobutyl stoppers and an aluminium flip-off caps, containing 50 ml of solution for infusion. Each 50 ml vial is packed into a cardboard carton.

SINORA 0,16 mg/ml is presented in Type I clear, colourless glass vials closed with bromobutyl stoppers and an aluminium flip-off caps, containing 50 ml of solution for infusion. Each 50 ml vial is packed into a cardboard carton.

Holder of Certificate of Registration

Umsebe Healthcare

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Name of Manufacturer: Sintetica SA

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SINORA 0,08 mg/ml: 56/5.1/0109

SINORA 0,16 mg/ml: 56/5.1/0110

Access to the corresponding Professional Information

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NAMIBIA:

SINORA 0,08 mg/ml (Solution for infusion): Reg. No.: 22/5.1/0012 NS2

SINORA 0,16 mg/ml (Solution for infusion): Reg. No.: 22/5.1/0013 NS2