PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

NORADRENALINE (NOREPINEPHRINE) EQUITY, 1 mg/mL concentrate for solution for infusion

Noradrenaline (norepinephrine) tartrate

Sugar free

Each mL of solution contains 3,3 mg of sodium, equivalent to 0,14 mmol.

Each 4 mL ampoule contains 13,2 mg of sodium, equivalent to 0,57 mmol.

Each 8 mL ampoule contains 26,4 mg of sodium, equivalent to 1,14 mmol.

Read all of this leaflet carefully before you are given NORADRENALINE (NOREPINEPHRINE) EQUITY

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

What is in this leaflet

1. What NORADRENALINE (NOREPINEPHRINE) EQUITY is and what it is used for

NORADRENALINE (NOREPINEPHRINE) EQUITY 1 mg/1 mL concentrate for solution for infusion is a medicine that belongs to the group of adrenergic and dopaminergic medicines and acts by narrowing the blood vessels.

NORADRENALINE (NOREPINEPHRINE) EQUITY is indicated for the emergency restoration of blood pressure in cases of acute hypotension (decreased blood pressure).

2. What you need to know before you are given NORADRENALINE (NOREPINEPHRINE) EQUITY

NORADRENALINE (NOREPINEPHRINE) EQUITY should not be administered to you:

- if you are hypersensitive (allergic) to noradrenaline (norepinephrine) or any of the other ingredients of NORADRENALINE (NOREPINEPHRINE) EQUITY (listed in section 6).
- if you if you are hypotensive (have low blood pressure) that has been caused by hypovolaemia (low blood volume).
- if you are going to receive anaesthetics such as halothane or cyclopropane (this may increase the risk of irregular heartbeat).

Warnings and precautions

Tell your doctor or healthcare provider before being given the injection: Special care should be taken with NORADRENALINE (NOREPINEPHRINE) EQUITY:

- tell your doctor if you experience any pain, stinging or burning at the injection site
- if you have major left ventricular dysfunction (a heart condition)
- if you suffer from clots or obstructions in your blood vessels
- if you have hypotension following a heart attack
- if you have Prinzmetal's variant angina (causes chest pain)
- if you have heart rhythm disorders during your treatment – you will need a reduced dose
- if you have hyperthyroidism (an overactive thyroid gland) or diabetes mellitus
- if you are elderly.

Your blood pressure and heart rate will be checked frequently during your treatment to avoid hypertension.

Children and adolescents

The safety and efficacy of NORADRENALINE (NOREPINEPHRINE) EQUITY in children and adolescents have not been established.

Other medicines and NORADRENALINE (NOREPINEPHRINE) EQUITY

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

- Halothane, cyclopropane: these medicines are anaesthetics, they cause insensibility to pain and are used before some operations. If you are receiving these medicines as well as noradrenaline this may increase the risk of irregular heart beat.
- Amitriptyline, imipramine, trimipramine, moclobemide, iproniazide, phenelzine, fluoxetine, sertraline: these medicines are used for treatment of depression. Taking any of these medicines together with NORADRENALINE (NOREPINEPHRINE) EQUITY can dangerously increase its concentration in the blood and therefore its pressor action (causing increase in blood pressure).
- Linezolid, an antibiotic (drug used to treat infections caused by bacteria and other microorganisms), can dangerously increase NORADRENALINE (NOREPINEPHRINE) EQUITY concentration in the blood and therefore its pressor action, when taken together.
- Alpha and beta-blockers (used to treat heart failure, hypertension): if you are taking these medicines as well as NORADRENALINE (NOREPINEPHRINE) EQUITY this may increase the risk of severe hypertension.
- Thyroid hormones, cardiac glycosides, anti-dysrhythmics: if you are taking these medicines as well as noradrenaline this may cause increased cardiac effects.
- Ergot alkaloids (used to treat severe headaches) or oxytocin (used in labour) may enhance the effects of NORADRENALINE (NOREPINEPHRINE) EQUITY.

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 healthcare provider for advice before receiving this medicine. The safety of NORADRENALINE (NOREPINEPHRINE) EQUITY in pregnancy and breastfeeding has not

been established.

Driving and using machines

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

NORADRENALINE (NOREPINEPHRINE) EQUITY 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 NORADRENALINE (NOREPINEPHRINE) EQUITY will be administered to you

You will not be expected to give yourself NORADRENALINE (NOREPINEPHRINE) EQUITY. It will be given to you by a person who is qualified to do so.

The dose of NORADRENALINE (NOREPINEPHRINE) EQUITY depends on the condition of the patient. Your doctor will know the best dose to use. NORADRENALINE (NOREPINEPHRINE) EQUITY is first diluted and then usually infused into a vein. The dose can then be adjusted using a pump according to the response to treatment, with the aim to establish a normal blood pressure.

If you use more NORADRENALINE (NOREPINEPHRINE) EQUITY than you should

Since a healthcare provider will administer NORADRENALINE (NOREPINEPHRINE) EQUITY, he / she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to use NORADRENALINE (NOREPINEPHRINE) EQUITY

Since a healthcare provider will administer NORADRENALINE (NOREPINEPHRINE) EQUITY, it is unlikely that the dose will be missed.

4. Possible side effects

NORADRENALINE (NOREPINEPHRINE) EQUITY can have side effects.

Not all side effects reported for NORADRENALINE (NOREPINEPHRINE) EQUITY are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using NORADRENALINE (NOREPINEPHRINE) EQUITY, please consult your healthcare provider for advice.

If any of the following happens, tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing
- severe headaches, dizziness, intense sweating, vomiting, pain in the chest or throat, paleness or loss of skin colour (pallor), abnormal sensitivity to light especially of the eyes.

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

Tell your doctor if you notice any of the following:

Side effects with unknown frequency:

- feeling anxious, weak, less alert
- problems with falling and staying asleep (insomnia)
- hallucinating, hearing voices, not thinking clearly, which may be signs of a psychotic state
- restricting your food intake (anorexia)
- headaches
- shaking or trembling movements in one or more parts of the body (tremor)
- changes in vision, blurred vision

- fast or slow heart rate
- breathlessness, swollen legs and feet and a bloated stomach, which may be early symptoms of a disease of the heart muscle
- confusion, restlessness, which may be caused by lower levels of oxygen
- gangrene (painful and cold extremities that may become purple to very dark/black, with tissue death)
- feeling sick (nausea)
- difficulty or increased frequency in passing urine
- pain, stinging, burning or swelling, redness, peeling skin, or liquid forming at the injection site.

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 "**Adverse drug reaction and quality problem reporting form**", found online under SAHPRA's publications: https://www.sahpra.org.za/document/adverse-drug-reactions-and-quality-problem-reporting-form/. By reporting side effects, you can help provide more information on the safety of NORADRENALINE (NOREPINEPHRINE) EQUITY.

5. How to store NORADRENALINE (NOREPINEPHRINE) EQUITY

Store all medicines out of reach of children.

Store at or below 25 °C.

Store in the original package to protect from light.

Do not use this medicine after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

After dilution:

The physicochemical stability of diluted product (in glucose 5 %, sodium chloride 9 mg/mL (0,9 %), or

sodium chloride 9 mg/mL with glucose 5 % solution) has been demonstrated for 48 hours at 30 °C. However, from a microbiological point of view, the diluted product should be used immediately. If the product is not used immediately, the duration and conditions of use are the sole responsibility of the user.
This product should be visually inspected prior to administration. Only a clear, colourless or slightly yellowish solution, free of particles or precipitates should be used. Do not use ampoules with a pink colour 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 (NOREPINEPHRINE) EQUITY contains

- The active substance is noradrenaline tartrate.
- Each mL of concentrate for solution for infusion contains 2 mg noradrenaline (norepinephrine) tartrate, equivalent to 1 mg noradrenaline base
- Each 4 mL ampoule contains 8 mg noradrenaline (norepinephrine) tartrate equivalent to 4 mg noradrenaline base.
- Each 8 mL ampoule contains 16 mg noradrenaline (norepinephrine) tartrate equivalent to 8 mg noradrenaline base.
- The other ingredients are sodium chloride, sodium hydroxide or hydrochloric acid and water for injections.

What NORADRENALINE (NOREPINEPHRINE) EQUITY looks like and contents of the pack

Clear, colourless or slightly yellowish solution, practically free from visible particles.

NORADRENALINE (NOREPINEPHRINE) EQUITY is packaged in type I clear glass, self-breaking (one point cut) ampoules of 5 mL and 10 mL, filled to 4 mL and 8 mL, respectively.
The glass ampoules are packed into carton boxes containing 10, 50 or 100 ampoules.
Not all pack sizes may be marketed.

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