

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S1

RUSAIN 10 mg/mL solution for injection/infusion

Phenylephrine hydrochloride.

Contains sodium metabisulphite (2 mg per 1 mL).

Sugar free.

Read all of this leaflet carefully before you are given RUSAIN

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

What is in this leaflet

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

1. What RUSAIN is and what it is used for

RUSAIN contains the active substance phenylephrine hydrochloride which belongs to a group of medicines known as vasoconstrictors.

RUSAIN is used to increase blood pressure in adults during clinically significant hypotension (low blood pressure) because of vasodilation during septic shock or anaesthesia.

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

RUSAIN should not be administered to you

- If you are hypersensitive (allergic) to phenylephrine hydrochloride or to any of the other ingredients of RUSAIN (listed in section 6).
- If you have uncontrolled high blood pressure.
- If you have an overactive thyroid (hyperthyroidism).
- If you have heart problems or heart failure.
- If you have a very slow heartbeat (less than 50 beats per minute).
- If you are under 18 years of age.

Warnings and precautions

Tell your doctor or health care provider before being given RUSAIN if:

- You have heart problems or conditions, including chest pain (angina pectoris).
- You have high blood pressure.
- You have an aneurysm (enlargement of an artery).
- You have Raynaud's phenomenon (decreased blood flow to the fingers or other parts, causing cold fingers or toes, colour changes in your skin, numb and prickly feeling or stinging pain upon warming).
- If you have diabetes mellitus or closed angle glaucoma.
- If you are allergic to sulphites.
- If you have been diagnosed with autonomic dysfunction (when your autonomic system does not work properly).

Children

RUSAIN is not recommended for use in children due to insufficient data on efficacy, safety and dose recommendations.

Other medicines and RUSAIN

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

Tell your doctor especially if you are taking:

- Monoamine oxidase inhibitors (MAOIs), such as selegiline, moclobemide, linezolid, nialamide, pargyline, phenelzine (used to treat depression). Tell your doctor if you are taking a MAOI or if you have taken them in the last 15 days.
- Medicines for your heart, such as digoxin (used to treat heart failure and a fast heartbeat) or quinidine (used to treat heart rhythm disorders).
- Medicines for depression, such as tricyclic antidepressants (amitriptyline, imipramine) or serotonin-norepinephrine reuptake inhibitors (NSRIs) (duloxetine, desvenlafaxine, venlafaxine).
- Medicines to treat high blood pressure.
- Antipsychotic medicines (haloperidol, phenothiazines).
- Atomoxetine (used to treat attention-deficit hyperactivity disorder (ADHD)).
- Antimuscarinic medicines, such as atropine (used to treat a slow heart rate).
- Lithium (used to treat some types of depression).
- Ergot alkaloids, such as ergotamine, dihydroergotamine, methylergometrine, methysergide (used to treat acute migraine (severe headache)) or bromocriptine (used to treat high levels of prolactin in the body) and cabergoline, lisuride, pergolide (used to treat Parkinson's disease).

Pregnancy and breastfeeding

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

Driving and using machines

It is not known if RUSAIN has an effect on the ability to drive or use machines. Do not drive or use machines until you know how RUSAIN affects you.

RUSAINE contains sodium metabisulphite

RUSAINE contains sodium metabisulphite which may rarely cause severe allergic reactions and bronchospasm.

3. How to use RUSAINE

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

RUSAINE will be given to you directly into a vein by an injection or infusion.

If you receive more RUSAINE than you should

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

If you forget to use RUSAINE

Since a health care provider will administer RUSAINE, it is unlikely that the dose will be missed.

4. Possible side effects

RUSAINE can have side effects.

Not all side effects reported for RUSAINE are included in this leaflet.

If any of the following happens, RUSAINE administration should be stopped and the patient should be managed at the hospital by a doctor or nurse:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing;
- rash or itching;
- fainting.

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

Tell your doctor immediately if you notice any of the following:

- cardiac arrest (pain in the chest, back, jaw and other areas of your upper body that lasts more than a few minutes or that goes away and comes back, shortness of breath),
- chest pain, changes in the way your heart beats, irregular heartrate,
- cerebral haemorrhage (sudden or severe headache, changes in vision or balance, seizures (fits), weakness or numbness in arms or legs),
- hypertensive crisis (chest pain, anxiety, headache, blurred vision, shortness of breath, nausea (feeling sick) and vomiting (being sick)),
- difficulty breathing, shortness of breath, wheezing, cough, cold and clammy skin.

Tell your doctor if you notice any of the following:

Frequent:

- headache.

Less frequent:

- anxiety, excitability, agitation, confusion, shaking (tremor),
- paraesthesia (tingling or numbness of your hands and feet (pins and needles),
- psychotic states (e.g. psychosis),
- dilated pupils, worsening of angle-closure glaucoma (increased pressure in the eye, causing headache, eye pain, blurred vision),
- high or low blood pressure,
- dizziness, fainting, flushing (redness of your skin),
- nausea (feeling sick), vomiting (being sick),
- sweating, pale skin, goosebumps,
- skin blanching (whitening of the skin),

- muscle weakness,
- difficulty in urinating or initiating urination.

Frequency unknown:

- metabolism and nutrition disorders, metabolic disorders,
- nervousness, restlessness, sleeplessness,
- an increase in saliva,
- painful or difficulty in passing urine,
- excessive sweating,
- injection site tissue damage,
- changes in blood sugar levels.

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

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist. This includes any possible side effects not listed in this leaflet. 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>.

5. How to store RUSAIN

- Store at or below 25 °C.
- Store all medicine out of reach of children.
- Do not use after the expiry date which is stated on the carton or ampoule.
- Do not dispose of unused medicines in drains, sewerage systems or household waste.
- Return all unused medicine to your pharmacist.

6. Contents of the pack and other information

What RUSAINE contains

The active substance is phenylephrine hydrochloride. Each 1 mL contains 10 mg phenylephrine hydrochloride.

The other ingredients are citric acid monohydrate (for pH-adjustment), sodium chloride, sodium citrate dihydrate (for pH-adjustment), sodium metabisulphite (E223) and water for injection.

What RUSAINE looks like and contents of the pack

RUSAINE is a clear, colourless solution.

1 mL clear Fiolax ampoule (USP Type I) with a pink OPC dot.

1 mL clear NEG ampoule (USP Type I) with a black OPC dot.

5 or 10 ampoules are placed in a plastic tray and packed in an outer carton.

Holder of certificate of registration

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LeBasi Pharmaceuticals (Pty) Ltd
RUSAIN 10 mg/mL

10 mg phenylephrine hydrochloride per 1 mL
Solution for injection/infusion

Date of registration

06 June 2023