APPROVED PATIENT INFORMATION LEAFLET:
DR. REDDY'S LABORATORIES (PTY) LTD.
NEUVYSI 200/500 (SOLUTION OF INJECTION)

SCHEDULING STATUS: S4

NEUVYSI 200, Solution for injection

NEUVYSI 500, Solution for injection

Sugammadex

Sugar free

Read all of this leaflet carefully before you are given NEUVYSI

- 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 NEUVYSI is and what it is used for

The active substance is sugammadex. NEUVYSI is considered to be a *Selective Relaxant Binding Agent* since it only works with specific muscle relaxants, rocuronium bromide or vecuronium bromide.

When you have some types of operations, your muscles must be completely relaxed. This makes it easier for the surgeon to do the operation. For this, the general anaesthetic you are given includes medicines to make your muscles relax. These are called *muscle relaxants*, and examples include rocuronium bromide and vecuronium bromide. Because these medicines also make your breathing muscles relax, you need help to breathe (artificial ventilation) during and after your operation until you can breathe on your own again. NEUVYSI is used to speed up the recovery of

your muscles after an operation to allow you to breathe on your own again earlier. It does this by combining with the rocuronium bromide or vecuronium bromide in your body. It can be used in adults whenever rocuronium bromide or vecuronium bromide is used and in children and adolescents (aged 7 to 17 years) when rocuronium bromide is used for a moderate level of relaxation.

2. What you need to know before you use NEUVYSI

NEUVYSI should not be administered to you

if you are hypersensitive (allergic) to sugammadex, or any of the other ingredients of NEUVYSI (listed in section 6).

Tell your healthcare provider if this applies to you.

Warnings and precautions

Talk to your healthcare provider before NEUVYS is given:

if you have kidney disease or had in the past. This is important as NEUVYSI is removed from your body by the kidneys.

if you have liver disease or have had it in the past.

If you have cardiovascular (heart and blood vessel) disease.

if you have fluid retention (oedema).

if you have diseases which are known to give an increased risk of bleeding (disturbances of blood clotting) or anticoagulation medication.

if you are on a controlled salt diet.

Children and adolescents

NEUVYSI should not be administered to patients below 7 years of age.

Use in elderly

Elderly patients can be given the same dose as other adults, provided their kidneys are working well.

Other medicines and NEUVYSI

Always tell your health care provider if you are taking any other medicine.

(This includes complementary or traditional medicines.)

Tell your healthcare provider if you are taking, have recently taken or might take any other medicines. NEUVYSI may affect other medicines or be affected by them.

Some medicines reduce the effect of NEUVYSI

It is especially important that you tell your healthcare provider if you have recently taken:

toremifene (used to treat breast cancer).

fusidic acid (an antibiotic).

NEUVYSI can affect hormonal contraceptives

NEUVYSI can make hormonal contraceptives - including the 'Pill', vaginal ring, implants or a hormonal IntraUterine System (IUS) - less effective because it reduces how much you get of the progestogen hormone. The amount of progestogen lost by using NEUVYSI is about the same as missing one oral contraceptive Pill.

If you are taking the **Pill** on the same day as NEUVYSI is given to you, follow the instructions for a missed dose in the Pill's package leaflet.

If you are using **other** hormonal contraceptives (for example a vaginal ring, implant or IUS) you should use an additional non-hormonal contraceptive method (such as a condom) for the next 7 days and follow the advice in the package leaflet.

Effects on blood tests

In general, NEUVYSI does not have an effect on laboratory tests. However, it may affect the results of a blood test for a hormone called progesterone and some blood clotting tests. Talk to your doctor if your progesterone levels need to be tested on the same day you receive NEUVYSI.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your healthcare provider for advice before receiving this medicine.

Tell your healthcare provider if you are pregnant or might be pregnant or if you are breast-feeding.

The safe use of this medicine in pregnant women has not been established.

It has not been studied whether sugammadex can pass into human breast milk, but it is expected based on animal studies.

Driving and using machines

NEUVYSI has no known influence on your ability to drive and use machines.

Your doctor or pharmacist will tell you when it is safe to drive or operate machinery after you have been given NEUVYSI.

NEUVYSI contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per 1 ml, that is to say essentially

'sodium-free'.

3. How NEUVYSI is given

NEUVYSI will be given to you by your healthcare provider.

The dose

Your healthcare provider will work out the dose of NEUVYSI you need based on:

your weight

how much the muscle relaxant medicine is still affecting you.

The usual dose is 2-4 mg per kg body weight. A dose of 16 mg/kg can be used in adults if urgent recovery from muscle relaxation is needed.

The dose of NEUVYSI for children is 2 mg/kg (children and adolescents between 7 -17 years old).

How NEUVYSI is given

NEUVYSI will be given to you by your healthcare provider. It is given as a single injection either directly into a vein or through an intravenous line.

If you receive more NEUVYSI than you should

As your healthcare provider will be monitoring your condition carefully, it is unlikely that you will be given too much NEUVYSI. But even if this happens, it is unlikely to cause any problems.

If you have any further questions on the use of this medicine, ask your healthcare provider.

4. Possible side effects

NEUVYSI can have side effects.

Not all side effects reported NEUVYSI are included in this leaflet.

If these side effects occur while you are under anaesthesia, they will be seen and treated by your healthcare provider.

Frequent side effects:

Cough

A temporary altered sense of taste

Airway difficulties that may include coughing or moving as if you are waking or taking a breath

Light anaesthesia - you may start to come out of deep sleep, so need more anaesthesia. This might cause you to move or cough at the end of the operation

Decreased blood pressure due to the surgical procedure.

Complications during your procedure such as changes in heart rate, coughing or moving

Less frequent side effects:

Shortness of breath due to muscle cramps of the airways (bronchospasm) occurred in patients with a history of lung problems

Allergic (drug hypersensitivity) reactions - such as a rash, red skin, swelling of your tongue and/or throat, shortness of breath, changes in blood pressure or heart rate, sometimes resulting in a serious decrease of blood pressure. Severe allergic or allergic-like reactions can be life threatening.

Allergic reactions were reported more commonly in healthy, conscious volunteers

Return of muscle relaxation after the operation.

Your muscles may be weakened for longer than expected after your operation

Anaesthetic complications during your procedure including severe slowing of the heart and slowing of the heart up to cardiac arrest

If you notice any side effects not mentioned in this leaflet, please inform your doctor, nurse or other healthcare provider.

Reporting of side effects

If you get side effects, talk to your doctor, nurse or other healthcare provider. 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 NEUVYSI.

5. How to store NEUVYSI

Storage will be handled by healthcare professionals.

Unopened vial:

Store at or below 25 °C.

Do not freeze.

Keep the vial in the outer carton in order to protect from light.

After reconstitution/dilution:

After first opening and dilution, store at 2 to 8 °C and use within 24 hours.

After first opening and dilution chemical and physical in-use stability has been demonstrated for 48 hours at 2 °C to 25 °C.

From a microbiological point of view, the diluted 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 °C to 8 °C, unless dilution has taken place in controlled and validated aseptic conditions

Discard any unused portion of the infusion solution.

Store all medicines out of reach of children.

6. Contents of the pack and other information

What NEUVYSI contains

The active substance is sugammadex.

1 ml solution for injection contains sugammadex sodium equivalent to 100 mg sugammadex.

Each vial of 2 ml contains sugammadex sodium equivalent to 200 mg sugammadex.

Each vial of 5 ml contains sugammadex sodium equivalent to 500 mg sugammadex.

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

What NEUVYSI looks like and contents of the pack

NEUVYSI 200 is packed in 2 ml tubular, Type-I glass vials with a 13 mm neck finish, sealed with 13 mm grey, teflon-coated rubber stoppers firmly sealed with flip-off seals.

NEUVYSI 500 is packed in 5 ml tubular, Type-I glass vials with a 20 mm neck finish, sealed with 20 mm grey, teflon-coated rubber stoppers firmly sealed ·with flip-off seals.

The rubber stoppers do not contain latex.

Pack sizes: 1 or 10 vials of 2 ml.

Pack sizes: 1 or 10 vials of 5 ml.

Not all pack sizes may be marketed.

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Holder of Certificate of Registration

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This leaflet was last revised in

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Registration numbers

NEUVYSI 200: 56/34/0214

NEUVYSI 500: 56/34/0215

Access to the corresponding Professional Information

Detailed information on this medicine is available on the Dr. Reddy's Laboratories (Pty) Ltd.

website: http://www.drreddys.co.za

For any information about this medicine, please contact the local representative of the Holder of

Certificate of Registration:

Dr. Reddy's Laboratories (Pty) Ltd. Tel: +27 11 324 2100