

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S4**

MUSCUDEx 100 mg/ml solution for injection

Sugammadex

Sugar free

Read all of this leaflet carefully before you are given MUSCUDEx

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

1. What MUSCUDEx is and what it is used for

MUSCUDEx is a medicine which falls under a group called selective relaxant binding medicines. It is used to speed up the recovery of your muscles after an operation by reversing the effects of the muscle relaxants, rocuronium or vecuronium.

It is also used for immediate reversal of the effects of rocuronium, 3 minutes after it has been administered to you.

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

MUSCUDEx should not be administered to you:

- If you are hypersensitive (allergic) to sugammadex or any of the other ingredients of MUSCUDEx listed in section 6.

Warnings and precautions

Tell your doctor or healthcare provider before being given the injection:

- If you have been diagnosed with severe kidney failure
- If you have been diagnosed with any heart conditions
- If you are taking medicines to thin your blood or have been diagnosed with any bleeding disorder
- If you have been diagnosed with a disease of the liver.

Tell your doctor if you feel like you have an abnormally slow heart rate after being given MUSCUDEx.

Children and adolescents

MUSCUDEx should not be used in children under the age of 7 years.

Other medicines and MUSCUDEx

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

(This includes all complementary or traditional medicines.)

The following medicines may decrease the effect of MUSCUDEx when given together:

- Toremifene - a medicine used to treat breast cancer
- Fusidic acid - an antibiotic

MUSCUDEx may reduce the effect of hormonal contraceptives including:

- The “pill”
- Vaginal ring
- Implants
- Patches
- Hormonal intrauterine devices (IUD).

If you are taking the pill on the same day as you are being given MUSCUDEx, follow the instructions for a missed dose on the package leaflet of the pill.

If you are using other hormonal contraceptives that are not taken orally (such as the vaginal ring, patches or implants), you should use an additional non-hormonal contraceptive method such as a condom for 7 days after you are given MUSCUDEx.

Effects on blood tests

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

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 taking this medicine.

The safety of MUSCUDEx in pregnant women is not known.

If you are pregnant or breastfeeding your baby, it is not advisable to receive MUSCUDEx. It is not known whether sugammadex can pass into breast milk.

Driving and using machines

There are no known effects of MUSCUDEx on the ability to drive or use machines. Ensure that you do not engage in these activities until you are aware of the extent to which MUSCUDEx affects you.

MUSCUDEx contains sodium

This medicine contains up to 9,3 mg sodium in each ml.

This is equivalent to 0,5 % of the WHO recommended maximum daily intake of 2 g sodium for an adult.

3. How to use MUSCUDEx

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

It is given into a vein (intravenously) as a single injection.

The appropriate dose for you will be determined by your doctor based on your weight and how much the muscle relaxant medicine is still affecting you.

Your doctor will tell you how long your treatment with MUSCUDEx will last.

If you have the impression that the effect of MUSCUDEx is too strong or too weak, tell your doctor or pharmacist.

If you are given more MUSCUDEx than you should receive

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

If you forget to take MUSCUDEx

Since a healthcare provider will administer MUSCUDEx, it is unlikely that the dose will be missed.

4. Possible side effects

MUSCUDEx can have side effects.

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

If any of the following happens, stop taking MUSCUDEx and tell your doctor immediately:

- Swelling of the hands, feet, face, lips or throat which may cause difficulty swallowing or breathing
- Severe itchy, lumpy rash (hives) or nettle rash (urticaria).

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

Other side effects of MUSCUDEx:

Frequent side effects:

- Continued the effects of rocuronium or vecuronium if an insufficient dose of MUSCUDEx is given
- Movement of the limbs or body during surgery
- Coughing during a procedure
- Suckling on the endotracheal tube
- Increased heart rate during the procedure
- Abnormally slow heart rate during the procedure
- Low blood pressure during the procedure

- Cough
- A change in taste.

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 MUSCUDEx.

5. How to store MUSCUDEx

Store all medicines out of reach of children.

Store at or below 25 °C.

Do not freeze.

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

6. Contents of the pack and other information

What MUSCUDEx contains

The active substance is sugammadex sodium equivalent to sugammadex 100 mg.

The other ingredients are: Hydrochloric acid (pH adjustment), sodium hydroxide (pH adjustment) and water for injection.

What MUSCUDEx looks like and contents of the pack

MUSCUDEx solution for injection is a clear, colourless to slightly yellow-brown solution.

MUSCUDEx solution for injection is packed in a type I colourless glass vial, sealed with a grey bromobutyl rubber stopper and with an aluminium flip-off cap.

MUSCUDEx is available in:

- 2 mL vials (200 mg/2 mL)
- 10 mL vials (500 mg/5 mL)

Pack sizes: 10 vials of 2 mL or 10 vials of 10 mL.

Not all pack-sizes may be marketed.

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This leaflet was last revised in

Date of registration: 10 September 2024

Registration number

59/34/0056

Namibia: S3 Reg. No.: TBA
