PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

REVERGAM 200 mg/2 mL solution for injection

REVERGAM 500 mg/5 mL solution for injection

Sugammadex sodium

Sugar free

Read all of this leaflet carefully before REVERGAM is administered to you:

- 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 REVERGAM is and what it is used for

REVERGAM belongs to a group of medicines called selective relaxant binding medicines and works with specific muscle relaxants, namely rocuronium bromide and vecuronium bromide.

REVERGAM is given to speed up your recovery from the muscle relaxant which is part of the

anaesthetic regimen to allow the surgeon to perform the operation. REVERGAM will be given to you at the end of an operation to allow you to breathe on your own again earlier. In children (above 7 years of age) REVERGAM can only be used in the instance where rocuronium bromide is used for a moderate level of relaxation.

2. What you need to know before REVERGAM is administered to you

REVERGAM should not be given to you:

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

Warnings and precautions:

Tell your doctor before REVERGAM is given to you:

- if you have a kidney disease or have had it in the past.
- if you have a slow heart rate (bradycardia).
- if you have a liver disease or have had it in the past.
- 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 if you are using anticoagulation medication.

You may experience a delay in recovery after REVERGAM is given to you:

- if you have a heart or blood vessel disease.
- if you are an elderly person.
- if you have a liver disease.

Children and adolescents:

REVERGAM can only be used in certain procedures and should not be used in children under 7 years of age.

Other medicines and REVERGAM:

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

Some medicines reduce the effect of REVERGAM. Tell your doctor if you are using:

- Toremifene (used to treat breast cancer).
- Fusidic acid (an antibiotic).

Contraceptives:

REVERGAM can affect hormonal contraceptives and make these contraceptives – including the 'pill', vaginal ring, implants or a hormonal intra uterine system (IUS) – less effective because it reduces how much you get of the progestogen hormone. The amount of progestogen lost by using REVERGAM is about the same as missing a dose of one oral contraceptive 'pill'. Therefore, if you are:

- Taking the 'pill' on the same day as REVERGAM is given to you, follow the instructions for a missed dose in the 'pill's' leaflet.
- 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.

Effect on blood tests:

REVERGAM do 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 REVERGAM.

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 other health care provider for advice before receiving REVERGAM.

It is not advisable to receive REVERGAM when you are pregnant or breastfeeding your baby.

Driving and using machines:

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

3. How REVERGAM is administered

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

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

REVERGAM is given into a vein (intravenously) or intravenous line as a single injection.

If you are given more REVERGAM than you should receive:

As your doctor will be monitoring your condition carefully, it is unlikely that you will be given too much REVERGAM.

4. Possible side effects

REVERGAM can have side effects.

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

If any side effects occur while you are under anaesthesia, they will be seen and treated by your doctor. Some side effects may also occur shortly afterwards; therefore, you will remain under supervision for a while after the operation.

If any of the following happens, stop receiving REVERGAM and tell your doctor immediately:

- 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 REVERGAM. You may need urgent medical attention or hospitalisation.

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

- Severe slowing of the heart and slowing of the heart up to cardiac arrest (abrupt loss of heart function, breathing and consciousness). Symptoms may include chest discomfort, shortness of breath, weakness and fast-beating or fluttering heart.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Side effects that may occur frequently:

- A temporary unpleasant taste in your mouth.
- Coughing.
- Complications during your procedure such as changes in heart rate, coughing or moving.
- Decreased blood pressure due to the surgical procedure.
- Airway difficulties that may include coughing or moving as if you are waking up.

Side effects that may occur less frequently:

- Your muscles may be weakened for longer than expected after the operation.
- Light anaesthesia – you may start to come out of deep sleep. This might cause you to move or cough at the end of the operation.

Other side effects where the frequency is unknown:

- 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 or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the "**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 REVERGAM.

5. How to store REVERGAM

- Store at or below 25 °C.
- Do not freeze.
- Keep the vial in the outer carton in order to protect from light. When not protected from light, the vial should be used within 5 days.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date printed on the carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What REVERGAM contains

The active substance is sugammadex sodium.

1 mL solution for injection contains 100 mg sugammadex (as sugammadex sodium).

Each 2 mL vial contains 200 mg sugammadex (as sugammadex sodium).

Each 5 mL vial contains 500 mg sugammadex (as sugammadex sodium).

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

What REVERGAM looks like and contents of the pack

A clear, colourless to slightly yellow-brown solution free from visible particles.

REVERGAM 200 mg/2 mL: 2 mL type I clear class vial with a 13 mm grey Chlorobutyl rubber stopper and sealed with a 13 mm aluminium seal, with a green polypropylene flip-off seal.
REVERGAM 500 mg/5 mL: 10 mL USP type I clear class vial with a 20 mm grey Chlorobutyl serum rubber stopper and sealed with a 20 mm aluminium seal, with a light blue polypropylene flip-off seal.

Pack sizes: 1 or 10 vials.

Not all pack sizes may be marketed.

Holder of certificate of registration

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Not applicable.

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REVERGAM 500 mg/5 mL: 55/2.11/0588.586

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05 September 2023