PATIENT INFORMATION LEAFLET FOR

SENUOM 2 mL and 5 mL (Solution for Injection)

SCHEDULING STATUS

S4

SENUOM 2 mL (200 mg/2 mL Solution for injection).

SENUOM 5 mL (500 mg/5 mL Solution for injection).

Sugammadex

Sugar free

Read all of this leaflet carefully before you are given SENUOM

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

What is in this leaflet

1. What SENUOM is and what it is used for

SENUOM 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 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 SENUOM

SENUOM should not be given to you:

- If you are hypersensitive (allergic) to sugammadex or any of the other ingredients of SENUOM.

Warnings and precautions

Tell your doctor before you are given SENUOM

- 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 SENUOM.

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

Other medicines and SENUOM

Always tell your healthcare professional if you are taking any other medicines.

(This includes all complementary or traditional medicines.)

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

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

SENUOM 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 SENUOM, 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 SENUOM.

Pregnancy and 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 professional for advice before you are given SENUOM

The safety of SENUOM in pregnant women is not known.

SENUOM may pass into your breast milk therefore you may need to stop breastfeeding for some time after being given SENUOM.

Driving and using machines

There are no known effects of SENUOM 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 SENUOM affects you.

3. How SENUOM is used

You will not be expected to give yourself SENUOM. 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.

If you are given more SENUOM than you should receive

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

If you forget to take SENUOM

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

4. Possible side effects

SENUOM can have side effects.

Not all side effects reported for SENUOM are included in this leaflet. Should your general health worsen or if you experience any untoward effects after being given SENUOM, please consult your doctor, pharmacist or other healthcare professional for advice.

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

- 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 SENUOM. You may need urgent medical attention, or hospitalisation.

Other side effects of SENUOM:

Frequent side effects:

- Continued the effects of rocuronium or vecuronium if an insufficient dose of SENUOM is given
- Movement of the limbs or body during surgery
- Coughing during a procedure
- Sucking of 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. 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:

http://www.sahpra.org.za/publications/index/8 or to Cipla Medpro (Pty) Ltd. by email: drugsafetysa@cipla.com or telephone: 080 222 6662 (toll free). By reporting side effects, you can help provide more information on the safety of SENUOM.

5. How to store SENUOM

Store all medicines out of reach of children.

Store at or below 25 °C.

Do not freeze.

Protect from light.

6. Contents of the pack and other information

What SENUOM contains:

The active substance is sugammadex

The other ingredients are:

Hydrochloric acid concentrate, nitrogen, sodium hydroxide and water for injection.

What SENUOM looks like and contents of the pack

SENUOM solution for injection is a clear and colourless to slightly yellow solution.

SENUOM 100 mg/mL solution for injection is packed in a type I glass vial with a Chlorobutyl rubber stopper and a one-piece aluminium seal with a coloured top plastic (flip-off) button. It is presented in packs containing 10 single-use vials in a carton box with a patient information leaflet.

SENUOM is available in:

- 2 mL single-use vials (200 mg/2 mL)
- 5 mL single-use vials (500 mg/5 mL).

Not all pack sizes will necessarily be marketed.

Holder of certificate of registration

CIPLA MEDPRO (PTY) LTD.

Building 9, Parc du Cap

Mispel Street

Belville

7530

Customer Care: 080 222 6662

This leaflet was last revised in

Not Applicable

Registration number(s)

To be allocated

Access to the corresponding professional information

To access corresponding Professional Information, scan the QR Code below.

PLACE HOLDER: The QR Code to be generated and included after approval.