Approved Patient Information Leaflet for Medicines for Human Use:

SESODEX

SCHEDULING STATUS:

S5

SESODEX 200 µg/2 mL concentrate for solution for infusion

Dexmedetomidine

Sugar Free

Read all of this leaflet carefully before you are given SESODEX

- 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 SESODEX is and what it is used for

SESODEX contains the active substance dexmedetomidine.

Dexmedetomidine is a sedative with analgesic (pain relieving) properties.

SESODEX is used for:

- To provide sedation for adult patients in hospital intensive care settings.
- To provide awake sedation during different diagnostic or surgical procedure.

2. What you need to know before you use SESODEX

SESODEX should not be administered to you

- If you are hypersensitive (allergic) to dexmedetomidine or any of the other ingredients of SESODEX (listed in section 6).
- if you have uncontrolled high blood pressure
- If you have any medical conditions that affect the blood vessels
- If you have any septic conditions
- If your condition is unstable following trauma injury
- If you have a condition called hypovolaemia, where there is a decrease in the amount of blood circulating through your body
- If you have been diagnosed with a condition called heart block
- If you have heart failure which cannot be controlled
- If you have loss of liver function

Warnings and precautions

Tell your doctor or health care provider before being given SESODEX**:**

- if you have liver or kidney problems
- if you are 65 years and older
- if you have high blood pressure
- if you have severe heart disease

Children and adolescents

Safety and efficacy of SESODEX has not been studied in children and adolescents and is therefore not recommended for patients under 18 years of age.

Other medicines and SESODEX

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

Tell your doctor if you are taking any of the following medicines:

- anaesthetics,
- sedatives,
- sleeping pills,
- certain pain relieving medicines,
- medicines used to control high blood pressure and those that affect the contraction of your heart

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 health care provider for advice before SESODEX is administered to you.

There is no information on fertility with SESODEX.

Driving and using machines

You should not drive or operate machinery or make legal decisions until 24 hours after recovery from surgical procedure in which SESODEX was used.

3. How to use SESODEX

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

Carefully follow all instructions given to you by your doctor, nurse or pharmacist.

Method of administration

You will not be expected to give yourself SESODEX

It will be given to you by a person who is qualified to do so.

A hospital pharmacist or doctor will have diluted the SESODEX concentrate before it is given to you.

SESODEX will be given to you as an infusion into a large vein.

The doctor will tailor the dose of SESODEX according to the level of sedation that needs to be achieved. At first, you will receive a higher dose over a period of 10 minutes. Once the desired level of sedation is achieved, the doctor will lower the dose in order to maintain the level of sedation.

If you have further questions on the use of SESODEX ask your doctor or pharmacist.

Duration of administration

Your doctor will tell you how long your treatment with SESODEX will last. If you have the impression that the effect of SESODEX is too strong or too weak, tell your doctor or pharmacist.

If you are given more SESODEX than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

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

If you forget to take SESODEX

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

If you stop taking SESODEX

Your doctor will tell you how long your treatment with SESODEX will last. If you have the impression that the effect of SESODEX is too strong or too weak, tell your doctor or pharmacist.

4. Possible side effects

SESODEX can have side effects.

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

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

- reduced heart function, heart attack or chest pain
- swelling of the stomach
- shortness of breath, change in breathing pattern or stopping breathing.

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

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- slow heart rate
- low or high blood pressure
- fast heart rate
- low or high blood sugar
- nausea, vomiting or dry mouth

- restlessness
- high temperature
- increased need to pass urine.
- symptoms after stopping the medicine

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- slow heart rate
- low or high blood pressure
- change in breathing pattern or stopping breathing.
- chest pain or heart attack
- fast heart rate
- low or high blood sugar
- nausea, vomiting or dry mouth
- restlessness
- high temperature
- symptoms after stopping the medicine

Less frequent side effects:

- reduced heart function, cardiac arrest
- swelling of the stomach
- thirst
- a condition where there is too much acid in the body
- low albumin level in blood
- shortness of breath

- hallucinations
- the medicine is not effective enough.

Side effects with frequency unknown:

- increased need to pass urine.

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 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 SESODEX

5. How to store SESODEX

- Store in the original packaging.
- Store at or below 25 °C. Protect from light
- Your doctor, pharmacist or healthcare professional knows how to store SESODEX**.** The doctor or nurse who is administering SESODEX to you, will make sure that the medicine is not used after the expiry date printed on the vial. They will also reconstitute SESODEX and visually inspect the solution before giving it to you. Only clear solution without particles will be used.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

6. Contents of the pack and other information

What SESODEX contains

- The active substance is dexmedetomidine.

- The other ingredients are sodium chloride and water for injection.

What SESODEX looks like and contents of the pack

SESODEX is a clear, colourless concentrated solution free of visible particles supplied in a colourless glass vial with a rubber stopper and flip-off seal.

200 µg/2 mL vials. (Pack size 4's and 25's)

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Austell Pharmaceuticals (Pty) Ltd

1 Sherborne Road

Parktown

JOHANNESBURG

2193

South Africa

Tel: 0860287835

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