PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S5

SEDMEDEX 100 µg/ml sterile solution for injection

Dexmedetomidine hydrochloride

Sugar free

Read all of this leaflet carefully before you are given SEDMEDEX

- 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 SEDMEDEX is and what it is used for

SEDMEDEX contains an active substance called dexmedetomidine which belongs to a medicine group called sedatives. It is used to provide sedation (a state of calm, drowsiness or sleep) for adult patients in hospital intensive care settings or awake sedation during different diagnostic or surgical

procedures.

2. What you need to know before you use SEDMEDEX

SEDMEDEX should not be administered to you:

- if you are hypersensitive (allergic) to dexmedetomidine or any of the other ingredients of SEDMEDEX (listed in section 6).
- 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 liver failure.
- if you have very low blood pressure which does not respond to treatment.
- if you have recently had a stroke or other serious condition affecting blood supply to the brain.

Warnings and precautions

Tell your doctor or health care provider before being given the injection:

- if you are 65 years and older.
- if you have diabetes.
- if you have high blood pressure.
- if you have severe heart disease.
- if you have a neurological disorder (for instance head or spinal cord injury or stroke).
- if you have severe liver problems.
- if you have ever developed a serious fever after some medicines, especially anaesthetics.

Other medicines and SEDMEDEX

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

The following medicines may enhance the effect of SEDMEDEX:

- medicines that help you sleep or cause sedation (e.g. midazolam, propofol)
- strong pain medicines (e.g. opioids such as morphine, codeine)
- anaesthetic medicines (e.g. isoflurane)

If you are using medicines which lower your blood pressure and heart rate, co-administration with SEDMEDEX may enhance this effect. SEDMEDEX should not be used with medicines that cause temporary paralysis.

Pregnancy, breastfeeding and fertility

You should not receive SEDMEDEX if you are pregnant or breastfeeding your baby.

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 SEDMEDEX.

Driving and using machines

SEDMEDEX has major impact on the ability to drive and use machines. After you have been given SEDMEDEX you must not drive, operate machinery, or work in dangerous situations until the effects are completely gone. Ask your doctor when you can start doing these activities again and when you can go back to this kind of work.

3. How to use SEDMEDEX

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

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

SEDMEDEX is diluted and it is given to you as an infusion (drip) into your veins.

Hospital intensive care

SEDMEDEX is administered to you by a doctor or nurse in hospital intensive care.

Procedural sedation/awake sedation

SEDMEDEX is administered to you by a doctor or a nurse prior to and/or during diagnostic or surgical procedures requiring sedation, i.e. procedural/awake sedation.

Your doctor will decide on a suitable dose for you. The amount of SEDMEDEX depends on your age, size, general condition of health, the level of sedation needed and how you respond to the medicine. Your doctor may change your dose if needed and will monitor your heart and blood pressure during the treatment.

After sedation/wake-up

- The doctor will keep you under medical supervision for some hours after the sedation to make sure that you feel well.
- You should not go home unaccompanied.
- Medicines to help you sleep, cause sedation or strong painkillers may not be appropriate for some time after you have been given SEDMEDEX. Talk to your doctor about the use of these medicines and about the use of alcohol.

If you receive more SEDMEDEX than you should

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

If you miss a dose of SEDMEDEX

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

4. Possible side effects

SEDMEDEX can have side effects.

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

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

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching.

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

Tell your doctor if you notice any of the following:

Frequent

- agitation,
- 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

- infections that may be serious (sepsis), fungal infection,
- anxiety, confusion, depression, nervousness,
- convulsions (fits), dizziness, headache, speech disorder,
- problems with vision,
- reduced heart function,
- swelling of the stomach,
- stomach pain, diarrhoea,
- thirst,
- a condition where there is too much acid in the body,
- low albumin level in blood,
- shortness of breath,
- hallucinations,
- rash, increased sweating,
- muscle weakness,
- the medicine is not effective enough,
- increased need to pass urine,
- pain, swelling,
- shivering, fever,
- fainting.

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 to SAHPRA via the "**6.04 Adverse Drug Reactions & Quality Problem Reporting Form**", found online under SAHPRA's publications:

https://sahpra.org.za/wp-content/uploads/2020/01/6.04_ARF1_v5.1_27Jan2020.pdf

By reporting side effects, you can help provide more information on the safety of SEDMEDEX.

5. How to store SEDMEDEX

Store all medicines out of reach of children.

- Store at or below 25 °C
- Keep the vials in the outer carton in order to protect from light.
- Do not use after the expiry date stated on the label or carton.

Once your doctor has diluted SEDMEDEX with a suitable solution, the solution should be used immediately, or may be stored in the refrigerator until ready to use. Any solution that is not used within 24 hours must be discarded.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What SEDMEDEX contains

- The active substance is dexmedetomidine.

Each 1 ml of sterile solution for injection contains dexmedetomidine hydrochloride equivalent to 100 micrograms dexmedetomidine.

Each 2 ml vial contains 200 micrograms of dexmedetomidine.

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

What SEDMEDEX looks like and contents of the pack

SEDMEDEX is a clear, colourless solution, free from visible extraneous matter.

SEDMEDEX is packed as 200 micrograms in 2 ml USP Type I clear glass vial, stoppered with 13 mm ready to sterilize grey colour rubber stopper sealed with 13 mm aluminium flip-off seal.

Pack size: 5 x 2 ml vials.

Holder of Certificate of Registration

Kahma Biotech (Pty) Ltd

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This leaflet was last revised in

21 February 2023

Registration number

540696

Access to the corresponding Professional Information

To follow