PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S5

EUSEDEX concentrated solution for intravenous infusion

Dexmedetomidine

Sugar free

Read all of this leaflet carefully before you receive EUSEDEX

- 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.
- EUSEDEX has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What EUSEDEX is and what it is used for

EUSEDEX is called an alpha$_2$-adrenoreceptor agonist. EUSEDEX is used for:

- sedation of patients in ICU who have undergone surgery and are on a mechanical ventilator
- for sedation when you receive certain surgical procedures under a local anesthesia or nerve block or when you receive a breathing tube while awake

2. What you need to know before you receive EUSEDEX

EUSEDEX should not be administered to you:

- if you are hypersensitive (allergic) to dexmedetomidine or any of the other ingredients of EUSEDEX (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 or are likely to have liver failure

If you are unsure if any of the list applies to you, ask your doctor. If you have any of the above, please tell your doctor or pharmacist.

Warnings and precautions

Take special care with EUSEDEX:

There are some medical conditions that may mean your doctor will need to monitor you more closely:

- if you have liver or kidney problems
- 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 experienced hyperthermia (high body temperature) or fever after receiving EUSEDEX or another similar medicine to calm you in the ICU, during surgery or other medical procedures.

Other medicines and EUSEDEX

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.) The use of EUSEDEX with these medicines may cause undesirable interactions.

EUSEDEX may interact with anaesthetics, sedatives, sleeping pills, certain painkillers, medicines used to control high blood pressure and those that affect the contraction of your heart. Tell your doctor or pharmacist if you are taking or have recently taken any of these medicines, or other medicines, including medicines obtained without a prescription or any herbal medicine.

Pregnancy and breastfeeding

EUSEDEX is not recommended in pregnancy, labour and delivery or for women who are 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 this medicine.

EUSEDEX passes into breast milk. If you have been exposed to EUSEDEX while breastfeeding, monitor your breastfed baby for signs of irritability (excessive crying and/or extreme fussiness).

Driving and using machines

Your ability to drive or to operate machinery may be impaired for some time. You should not drive or make any legal decisions until your doctor advises that you may do so, usually this is 24 hours after recovery from a surgical procedure in which EUSEDEX was used.

It is not always possible to predict to what extent EUSEDEX may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which EUSEDEX affects them.

3. How to receive EUSEDEX

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

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

During the administration of EUSEDEX, your vital signs (blood pressure, heart rate and oxygen levels) will be monitored.

You should never receive EUSEDEX as an injection; it will be given to you as a drip and may even be given via a device that accurately controls the drip rate.

You should never receive EUSEDEX if it is discoloured or contains visible solid particles in the solution.

You should not be given EUSEDEX for longer than 24 hours.

Dosage

The doctor will tailor the dose of EUSEDEX according to the level of sedation he needs to achieve. 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.

Your doctor and/or nurse will monitor blood pressure, heart rate and oxygen levels, both continuously during the infusion of EUSEDEX and as clinically appropriate after discontinuation.

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

If you receive more EUSEDEX than you should

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

If you forget to use EUSEDEX

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

4. Possible side effects

EUSEDEX can have side effects.

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

Tell your doctor if you notice any of the following:

The most commonly reported side effects that are thought to be medicine-related are:

- high blood pressure
- low blood pressure
- a slower than normal heartbeat
- nausea
- dry mouth
- low oxygen levels in the body tissues

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 or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reactions 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 EUSEDEX.

5. How to store EUSEDEX

- Store all medicines out of reach of children.
- EUSEDEX should be stored in its original container at room temperature (at or below 25 ^{o}C).
- Once your doctor has diluted EUSEDEX 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.

6. Contents of the pack and other information

What EUSEDEX contains

- The active substance is dexmedetomidine hydrochloride. Each 1 mL of EUSEDEX concentrated solution contains dexmedetomidine hydrochloride equivalent to 100 micrograms dexmedetomidine.
- The other ingredients are water for injections and sodium chloride.

What EUSEDEX looks like and contents of the pack

EUSEDEX is a clear and colourless concentrated solution.

EUSEDEX is available in 2 mL glass vials. Each pack may contain either 5 or 25 units.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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