PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S5

DEXITHERA 100 µg/mL 2 mL concentrate for solution for infusion

DEXITHERA 100 µg/mL 4 mL concentrate for solution for infusion

DEXITHERA 100 µg/mL 10 mL concentrate for solution for infusion

Dexmedetomidine

Sugar free

Read all of this leaflet carefully before you are given DEXITHERA 100 µg/mL

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

What is in this leaflet

6. Contents of the pack and other information

1. What DEXITHERA 100 µg/mL is and what it is used for

DEXITHERA 100 µg/mL contains the active substance dexmedetomidine that belongs to a group of medicines called sedatives. It is used to provide sedation (a state of calm, drowsiness or sleep) for adult patients in hospital intensive care (ICU) settings or awake sedation during surgical procedures. Awake sedation is a state where a person remains awake and aware without feeling discomfort or pain.

2. What you need to know before you are given DEXITHERA 100 µg/mL

DEXITHERA 100 µg/mL should not be administered to you if:

- You are hypersensitive (allergic) to dexmedetomidine or any of the other ingredients of DEXITHERA 100 µg/mL listed in section 6 of this leaflet.
- You have sepsis.
- You are an unstable trauma patient.
- You have a low blood volume.
- You have heart block (a disorder of your heart rhythm).
- You have uncontrolled cardiac failure.
- You have liver problems.

Warnings and precautions

Tell your doctor or heath care provider before being given DEXITHERA 100 µg/mL:

- If you have an abnormally slow heart rate (either due to illness or high levels of physical fitness).

- If you have low blood pressure.
- If you have low blood volume, for example after bleeding.
- If you have certain heart disorders.
- If you are elderly.
- 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.
- If you suffer from dry eyes.

Avoid use of any other sedative medicines and substances (such as alcohol, opioid medicine or benzodiazepines) for a at least 24 hours after you have been given DEXITHERA 100 µg/mL.

Children and adolescents

DEXITHERA 100 µg/mL should not be given to children and adolescents under the age of 18.

Other medicines and DEXITHERA 100 µg/mL

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 DEXITHERA 100 µg/mL:

- Medicines to help you sleep or cause sedation (such as midazolam, propofol).

- Strong pain medicines (e.g., opioids, such as morphine, codeine).
- Anaesthetic medicines (such as sevoflurane, isoflurane).
- Medicine to lower your blood pressure.
- Medicine to lower your heart rate (such as beta-blockers).

DEXITHERA 100 µg/mL with food, drink and alcohol

The use of alcohol during and after treatment with DEXITHERA 100 µg/mL should be avoided for at least 24 hours.

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 being given DEXITHERA 100 µg/mL.

DEXITHERA 100 µg/mL should not be administered during pregnancy, labour and breastfeeding.

Driving and using machines

DEXITHERA 100 µg/mL has a major impact on the ability to drive and use machines. After you have been given DEXITHERA 100 µg/mL, you must refrain from driving, operating machines, doing any other hazardous tasks or making legal decisions for at least 24 hours.

DEXITHERA 100 µg/mL contains sodium

DEXITHERA 100 µg/mL contains less than 1 mmol sodium (23 mg) per ampoule or vial, that

is to say essentially `sodium-free´.

DEXITHERA 100 µg/mL contains 37 mg sodium (main component of cooking/table salt) in each 10 mL vial. This is equivalent to 2 % of the recommended maximum daily dietary intake of sodium for an adult.

3. How to use DEXITHERA 100 µg/mL

You will not be expected to give yourself DEXITHERA 100 µg/mL. It will be given to you by a person who is qualified to do so.

Procedural sedation/awake sedation

DEXITHERA 100 µg/mL 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.

DEXITHERA 100 µg/mL is diluted and it is given to you as an infusion (drip) into your veins. Before being given DEXITHERA 100 µg/mL, your health care provider may give you fluid supplementation to ensure that your blood volume is normal.

Your doctor will decide on a suitable dose for you. The amount of DEXITHERA 100 µg/mL 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 DEXITHERA 100 µg/mL. Talk to your doctor about the use of these medicines and about the use of alcohol.

If you receive more DEXITHERA 100 µg/mL than you should

Since a health care provider will administer DEXITHERA 100 µg/mL, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage. If you are given too much DEXITHERA 100 µg/mL, your blood pressure may go up or down, your heartbeat may slow down, you may breathe more slowly and you may feel more drowsy.

If you forget to use DEXITHERA 100 µg/mL

Since a health care provider will administer DEXITHERA 100 µg/mL, it is unlikely that the dose will be missed.

If you stop using DEXITHERA 100 µg/mL

Withdrawal symptoms may occur following prolonged use and abrupt discontinuation of DEXITHERA 100 µg/mL. Withdrawal symptoms include feeling agitated and developing a temporary high blood pressure, headache and nervousness.

4. Possible side effects

DEXITHERA 100 µg/mL can have side effects.

Not all side effects reported for DEXITHERA 100 µg/mL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking DEXITHERA 100 µg/mL, please consult your health care provider for advice.

If any of the following happens, tell your doctor immediately as infusion with DEXITHERA 100 µg/mL should be stopped:

- swelling of your hands, feet, ankles, face, lips, 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 allergic reaction to DEXITHERA 100 µg/mL. 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:

- changes in the way your heart beats, if you notice it beating slower or faster;
- chest pain, heart attack or cardiac arrest (pain in the chest, back, jaw and other areas of your upper body that lasts more than a few minutes or that goes away and comes back, shortness of breath);
- shortness of breath, wheezing, slow or rapid breathing, difficulty breathing;

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:

- hypovolaemia (decreased blood volume, causing fatigue, a rapid heartrate, cool and clammy skin);
- high fever, headache, flushing of your skin and chills;
- withdrawal syndrome (causing agitation, headaches and nervousness);
- abnormal bleeding following surgery;
- high or low blood sugar;
- an increase or decrease of your blood pressure;
- anaemia (feeling tired, shortness of breath and a pale colour of your skin);
- nausea (feeling sick), vomiting (being sick) and dry mouth;
- feeling agitated.

Less frequent side effects:

- hypoalbuminaemia (low albumin level in the blood);
- metabolic acidosis (a condition where there is too much acid in the body);
- fluid retention (causing swelling of your hands, ankles and feet);
- decrease in urine volume;
- changes in your blood calcium levels when monitored;
- hallucinations (seeing or hearing things that aren’t real); abdominal distention (swelling of your stomach); thirst.
- If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist

Side effects with unknown frequency:

- Urinating more than usual.

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 Health care provider. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of DEXITHERA 100 µg/mL.

Abbott Laboratories South Africa Pharmacovigilance:

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5. How to store DEXITHERA 100 µg/mL

- Store at or below 30 °C.
- Store all medicines out of reach of children.
- Do not use after the expiry date printed on the ampoule, vial or carton.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What DEXITHERA 100 µg/mL contains

The active substance in DEXITHERA 100 µg/mL is dexmedetomidine.

Each 2 mL ampoule contains 200 micrograms of dexmedetomidine.

Each 4 mL vial contains 400 micrograms of dexmedetomidine.

Each 10 mL vial contains 1 000 micrograms of dexmedetomidine.

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

What DEXITHERA 100 µg/mL looks like and contents of the pack

Clear, colourless solution, pH 4,5 – 7,0.

DEXITHERA 100 µg/mL 2 mL ampoule: 2 mL colourless Type I glass ampoule with a light blue ring.

DEXITHERA 100 µg/mL 4 mL or 10 mL vials: 4 mL or 10 mL Type I glass vial (with filling volumes of 4 and 10 mL) with a grey bromobutyl rubber stopper with fluoropolymer coating and blue aluminium flip off seal.

The ampoules/vials are packed in a cardboard carton.

Pack sizes:

5 x 2 mL ampoules

25 x 2 mL ampoules

4 x 4 mL vials

4 x 10 mL vials

Not all pack sizes may be marketed.

Holder of certificate of registration

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