PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S5

DEXSEDATE 100 µg/ml concentrate for solution for infusion

Dexmedetomidine

Sugar free

Read all of this leaflet carefully before you are given DEXSEDATE

- 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 DEXSEDATE is and what it is used for

DEXSEDATE contains an active substance called dexmedetomidine which belongs to a group of medicine 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 DEXSEDATE

DEXSEDATE should not be administered to you:

- if you are hypersensitive (allergic) to dexmedetomidine or any of the other ingredients of DEXSEDATE (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 uncontrolled low blood pressure.
- if you suddenly develop blood vessel diseases in 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 or low blood pressure.
- 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 have less tear production or flow of tears, which may cause dryness of the eye.

- if you develop agitation and high blood pressure shortly after stopping DEXSEDATE.

Children and adolescents

The safety and efficacy of DEXSEDATE have not been fully studied in children and adolescents and are, therefore, not recommended for patients under 18 years of age.

Other medicines and DEXSEDATE

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 DEXSEDATE:
- 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. sevoflurane, isoflurane)

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

Pregnancy, breastfeeding and fertility

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

No human data on fertility are available, there was however no effect on rat fertility in males and females.

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 DEXSEDATE.

Driving and using machines

DEXSEDATE has major impact on the ability to drive and use machines. After you have been given DEXSEDATE 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.

It is not always possible to predict to what extent DEXSEDATE 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 DEXSEDATE affects them.

DEXSEDATE contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially “sodium free”.

3. How to use DEXSEDATE

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

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

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

Hospital intensive care

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

Procedural sedation/awake sedation

DEXSEDATE 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 DEXSEDATE 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 DEXSEDATE. Talk to your doctor about the use of these medicines and about the use of alcohol.

If you receive more DEXSEDATE than you should

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

If you miss a dose of DEXSEDATE

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

4. Possible side effects

DEXSEDATE can have side effects.

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

If any of the following happens, stop receiving DEXSEDATE 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 DEXSEDATE. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent

- low levels of healthy red blood cells or haemoglobin,
- agitation,
- slow heart rate,
- low or high blood pressure,
- change in breathing pattern or stopping breathing,
- fast heart rate,
- low or high blood sugar,
- nausea, vomiting or dry mouth,
- high body temperature, fever,
- chills,
- collapse of a lung or part of a lung,
- pleural effusion (an abnormal build-up of fluid in the space around your

lungs),

- hypoxia (tissues and cells do not get enough oxygen to function correctly), symptoms include shortness of breath and unexplained exhaustion.
- bradypnea (an abnormally slow breathing rate),
- post-operative bleeding.

Less frequent

- low albumin levels in the blood,
- low calcium levels in the blood,
- swelling of the stomach,
- thirst,
- heart problems,
- shortness of breath,
- the medicine is not effective enough,
- decreased volume of urine,
- metabolic acidosis (a condition where there is too much acid in the body),
- excessive fluid accumulation in the lungs,
- wheezing (whistling sound when you breathe),
- apnea (temporary cessation of breathing),
- accumulation of interstitial fluid.

Frequency unknown

- infections that may be serious (sepsis), fungal infection,
- blood and clotting disorders,
- low or high potassium levels in the body,
- low sodium levels in the body,
- a decrease of the quantity of proteins in your blood,

- anxiety, confusion, depression, nervousness, hallucinations
- convulsions (fits), dizziness, headache, speech disorder,
- pain, swelling, tingling, pins-and-needles, muscle weakness, tiredness, cramps, and muscle twitch,
- rash, increased sweating,
- shivering, fever,
- problems with vision,
- chest pain or heart attack,
- reduced heart function, disturbances or abnormal heart rhythm,
- blood pressure fluctuation, low or high blood pressure and bleeding,
- increased sputum, other lung illnesses,
- stomach pain, diarrhoea, mouth ulcers,
- diabetes,
- fainting,
- liver function problems, jaundice,
- kidney function problems, urinary retention (a condition in which you are unable to empty all the urine from your bladder),
- ascites (a buildup of fluid in the abdominal cavity),
- rigors (a sudden feeling of cold with shivering accompanied by a rise in temperature),
- delirium (a serious change in mental abilities),
- illusion (a false idea or belief),
- light anaesthesia (the loss of normal sensation or feeling),
- symptoms after stopping the medicine (nervousness, agitation and headache accompanied or followed by a rapid rise in blood pressure).

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 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 DEXSEDATE.

5. How to store DEXSEDATE

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 DEXSEDATE 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 DEXSEDATE contains

- The active substance is dexmedetomidine.

  Each 1 ml of concentrate for solution for infusion contains dexmedetomidine hydrochloride equivalent to 100 µg dexmedetomidine.

  Each 2 ml ampoule contains 200 µg of dexmedetomidine.

  Each 5 ml vial contains 500 µg of dexmedetomidine.

  Each 10 ml vial contains 1 000 µg of dexmedetomidine.

- The other ingredients are hydrochloric acid, sodium chloride, sodium hydroxide

and water for injection.

What DEXSEDATE looks like and contents of the pack

DEXSEDATE is a clear, colourless solution, free from visible particles and fibers.

DEXSEDATE is packed in 2 ml type I clear glass ampoules with a white colour dot, 5 ml or 10 ml type I clear vials with grey colour rubber stoppers and aluminium flip-off white seals.

Pack size: 5 x 2 ml ampoules, 5 x 5 ml vials or 5 x 10 ml vials.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

https://www.pharmaq.co.za