1.3.2.1 Approved Patient Information Leaflet

SCHEDULING STATUS: S5

PREXUJECT™ 200 µg/50 ml RTU, solution for infusion

PREXUJECT™ 400 µg/100 ml RTU, solution for infusion

Dexmedetomidine, as dexmedetomidine hydrochloride

Sugar free

Read all of this leaflet carefully before you are given PREXUJECT

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

What is in this leaflet:

1. What PREXUJECT is and what it is used for

2. What you need to know before you are given PREXUJECT

3. How to use PREXUJECT

4. Possible side effects

5. How to store PREXUJECT

6. Contents of the pack and other information

1. What PREXUJECT is and what it is used for

PREXUJECT contains an active substance called dexmedetomidine which belongs to a medicine group called sedatives.

PREXUJECT is used:

- to provide sedation (a state of calm, drowsiness or sleep) for adult patients in hospital intensive care (ICU) who have undergone surgery and are on a mechanical ventilator
- or awake sedation during different diagnostic or certain surgical procedures under a local anaesthesia or nerve block or when you receive a breathing tube while awake.

2. What you need to know before you are given PREXUJECT

PREXUJECT should not be administered to you:

- if you are hypersensitive (allergic) to dexmedetomidine or any of the other ingredients of PREXUJECT (listed in section 6)
- if you have sepsis (that is a condition where your body has an unusually severe response to an infection)
- if your condition is unstable after a traumatic injury
- if you have hypovolemia (an abnormal depletion of fluid in the body that reduces the amount of blood circulating through your body)
- if you have been diagnosed with disorders of the heart rhythm (heart block grade 2 or 3)
- if you have uncontrollable heart failure
- if you have or are likely to have liver failure

Warnings and precautions

Special care should be taken with PREXUJECT

Tell your doctor or healthcare provider before being given the infusion:

- if you have liver or kidney problems
- if you have an abnormally slow heart rate (either due to illness or high levels of physical fitness) as it may increase the risk for cardiac arrest

- if you also receive medicines that cause low blood pressure and a slow heart rate, such as beta-blockers (for example, esmolol)
- if you are elderly (65 years or older)
- if you have low blood pressure
- if you have diabetes insipidus and/or polyuria (large amount of urine) or excessive thirst. Contact a doctor if these side effects occur. See section 4 for more information.
- if you have diabetes mellitus
- if you have high blood pressure
- if you have severe heart disease
- if you have low blood volume, for example after bleeding

You may experience dry eyes and may need lubricating eye drops when you are being administered PREXUJECT.

An increased mortality risk has been seen for patients 65 years of age and under when using PREXUJECT, especially for patients admitted to the intensive care unit for other reasons than after surgery with a more severe disease condition on admission to the intensive care unit and with a younger age.

Your doctor will decide if this medicine is still suitable for you. The doctor will consider the benefits and risks of PREXUJECT for you, compared to treatment with other sedatives.

Other medicines and PREXUJECT

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

The following medicines may enhance the effect of PREXUJECT:

- 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)
- medicines used to control high blood pressure and those that affect the contraction of your heart.

If you are using medicines which lower your blood pressure and heart rate, co-administration with PREXUJECT may enhance this effect.

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 receiving PREXUJECT.

PREXUJECT should not be used during pregnancy or breastfeeding.

Driving and using machines

PREXUJECT has a major impact on the ability to drive and use machines. After you have been given PREXUJECT you must not drive, operate machinery, or work in dangerous situations or make legal decisions until the effects are completely gone (usually after 24 hours). Ask your doctor when you can start doing these activities again and when you can go back to this kind of work.

PREXUJECT contains sodium

PREXUJECT contains less than 1 mmol sodium (23 mg) per ml, that is to say essentially ‘sodium-free’.

3. How to use PREXUJECT

Hospital intensive care

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

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

Procedural sedation/awake sedation

PREXUJECT 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 PREXUJECT 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.

PREXUJECT is given to you as an infusion (drip) into your veins.

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 PREXUJECT. Talk to your doctor about the use of these medicines.

If you have been given more PREXUJECT than you should

Since a healthcare provider will administer PREXUJECT, he / she will control the dosage.

If you are given too much PREXUJECT, your blood pressure may go up or down, your heartbeat may slow down, you may breathe more slowly and you may feel drowsier. Your doctor will know how to treat you based on your condition.

4. Possible side effects

PREXUJECT can have side effects.

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

If any of the following happens, your doctor will treat you immediately:

- 'swelling of the hands, feet, ankles, face, lips and 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 reaction to PREXUJECT. 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:

- chest pain,
- angina,
- changes in the way your heart beats, for example, if you notice it beating faster,
- yellowing of the skin and eyes, dark urine, and tiredness which may be symptoms of liver problems.

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

- low or high blood sugar
- restlessness
- slow heart rate
- chest pain or heart attack

- fast heart rate
- low or high blood pressure
- change in breathing pattern or stopping breathing.
- nausea, vomiting or dry mouth
- high temperature
- withdrawal symptoms after stopping the medicine.

Less frequent side effects

- a condition where there is too much acid in the body
- low albumin level in blood
- hallucinations
- reduced heart function, cardiac arrest
- shortness of breath
- swelling of the stomach
- thirst
- the medicine is not effective enough.

Not known (frequency cannot be estimated from the available data):

- infection, fungal infection, sepsis
- large amount of urine and excessive thirst – may be symptoms of a hormonal disorder called diabetes insipidus. Contact a doctor if these occur.
- problems with blood clotting
- various blood disorders (seen in laboratory tests)
- diabetes mellitus, high blood sugar, low blood sugar
- increased or decreased potassium in blood
- anxiety, confusion, coma,

- depression, nervousness
- convulsion, dizziness
- headache
- nerve pain, inflammation of the nerves
- paralysis, partial paralysis, speech disorder,
- bleeding problems
- problems with blood circulation in arms and legs
- widening of the arteries
- various respiratory/lung disorders (obstruction, coughing, water on the lungs, problems breathing, increased sputum, noisy breathing)
- abdominal pain, diarrhoea, belching, ulcers in mouth
- liver function tests abnormal
- increased sweating
- muscle weakness
- kidney function tests abnormal
- more urine than usual or bladder does not empty completely
- swollen belly, swollen legs and arms
- shaking, chills.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get any side effects talk to your doctor, pharmacist or nurse. 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 PREXUJECT.

5. How to store PREXUJECT

Store all medicines out of reach of children.

Store at or below 30 °C. Keep the vial in the original container until required for use.

PREXUJECT will be stored and handled by your healthcare practitioner.

Do not use this medicine after the expiry date which is stated on the label and carton after EXP.

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

6. Contents of the pack and other information

What PREXUJECT contains

- The active substance is dexmedetomidine. Each ml of the ready-for-use solution contains 4 micrograms/ml.
- The other ingredients are sodium chloride and water for injection.

What PREXUJECT looks like and contents of the pack

Ready-to-use solution for intravenous infusion.

The solution is clear and colourless.

PREXUJECT is packed in Type I transparent glass vials with 50 ml and 100 ml capacity, closed by coated chlorobutyl rubber stoppers and sealed by aluminium caps.

Each 50 ml vial contains 200 micrograms of dexmedetomidine in 50 ml solution.

Each 100 ml vial contains 400 micrograms of dexmedetomidine in 100 ml solution.

Pack sizes:

1, 5, 10 or 25 vials of 50 ml packed in carton boxes.

1, 5, 10 or 25 vials of 100 ml packed in carton boxes

Not all pack sizes may be marketed.

Holder of the Certificate of Registration

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PREXUJECT™ 200 µg/50 ml RTU: 59/2.9/0098.096

PREXUJECT™ 400 µg/100 ml RTU: 59/2.9/0099.097

Access to the corresponding Professional Information

For Professional Information (PI), please refer to https://medsinfo.sahpra.org.za/home, or scan the QR code: