

PATIENT INFORMATION LEAFLET**SCHEDULING STATUS****S5****SEDMEDEX RTU 50 mL and SEDMEDEX RTU 100 mL solution for infusion 4 µg/mL****Dexmedetomidine hydrochloride****Sugar free****Read all of this leaflet carefully before you are given SEDMEDEX RTU**

- 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 RTU is and what it is used for
2. What you need to know before you receive SEDMEDEX RTU
3. How to receive SEDMEDEX RTU
4. Possible side effects
5. How to store SEDMEDEX RTU
6. Contents of the pack and other information

1. What SEDMEDEX RTU is and what it is used for

SEDMEDEX RTU is called an α_2 -adrenoreceptor agonist. SEDMEDEX RTU 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 SEDMEDEX RTU

SEDMEDEX RTU should not be administered to you:

- if you are hypersensitive (allergic) to dexmedetomidine or any of the other ingredients of SEDMEDEX RTU (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 SEDMEDEX RTU:

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 low blood pressure
- if you have severe heart disease

- 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 have a neurological disorder (for instance head or spinal cord injury or stroke)
- if you have ever developed a serious fever after some medicines, especially anaesthetics.

This medicine may cause large amount of urine and excessive thirst, contact a doctor if these side effects occur.

Other medicines and SEDMEDEX RTU

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

SEDMEDEX RTU 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.

Pregnancy and breastfeeding

SEDMEDEX RTU 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 SEDMEDEX RTU.

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 SEDMEDEX RTU was used.

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

3. How to receive SEDMEDEX RTU

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

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

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

You should never receive SEDMEDEX RTU 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 not be given SEDMEDEX RTU for longer than 24 hours.

Dosage

The doctor will tailor the dose of SEDMEDEX RTU 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 SEDMEDEX RTU and as clinically appropriate after

discontinuation.

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

If you receive more SEDMEDEX RTU than you should

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

If you forget to use SEDMEDEX RTU

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

4. Possible side effects

SEDMEDEX RTU can have side effects.

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

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

- swelling of the hands, feet, ankles, face, lips, tongue 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 SEDMEDEX RTU. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent

- Lack of red blood cells in the blood (anaemia)
- low blood sugar or high blood sugar
- agitation
- abnormal heart rhythm, failing condition of the heart muscle, slow heart rate, faster than normal heartbeat
- low blood volume
- high blood pressure
- low blood pressure
- lung collapse, excess fluid in the cavity of the lungs, low level of oxygen in the blood, abnormally slow breathing rate, hypoventilation
- nausea, vomiting
- dry mouth
- fever, chills, overheating
- withdrawal syndrome
- bleeding after surgery

Less frequent

- low calcium levels in the blood
- low level of albumin in the blood
- excess acid in the body fluids
- hallucinations
- various heart disorders, heart stops beating

- excess fluid in the lungs
- wheezing, shortness of breath, sleep disorder
- swollen stomach
- swelling of the lower limbs and hands
- thirst
- decreased urine output

Frequency unknown

- infections, fungal infections, blood poisoning
- various abnormalities of the blood cells
- metabolic disease that causes high blood sugar
- an imbalance of water in the body
- too much acid in the body
- anxiety, confusion, seeing or hearing things that aren't real, depression, distortion of the senses, nervousness
- fits
- dizziness, headache
- nerve pain, inflammation of the nerve, nerve damage
- pins and needles, loss of muscle function, muscle weakness
- speech disorder
- abnormal vision
- various heart disorders, including abnormal heart rhythm
- low oxygen levels in the body tissues
- bleeding
- widening of blood vessels
- fainting
- adult respiratory distress syndrome, airway obstruction

- coughing, coughing up blood, shortness of breath
- lung disorders due to infection or inflammation, increased phlegm
- painful stomach, diarrhoea, burping, mouth sores
- abnormal liver function tests
- jaundice (yellowing of the skin and eyes)
- rash
- increased sweating
- abnormal kidney function, urinary retention
- buildup of fluid in your belly
- pain

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 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 SEDMEDEX RTU.

5. How to store SEDMEDEX RTU

Store all medicines out of reach of children.

- Store at or below 25 °C
- Do not use after the expiry date stated on the label/carton

Do not use SEDMEDEX RTU if you notice particulate matter or discolouration.

Return all unused medicine to your pharmacist; vials are intended for single patient use

only.

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

6. Contents of the pack and other information

What SEDMEDEX RTU contains

- The active substance is dexmedetomidine hydrochloride.
- The other ingredients are sodium chloride and water for injection.

What SEDMEDEX RTU looks like and contents of the pack

SEDMEDEX RTU is a clear, colourless solution.

SEDMEDEX RTU 50 mL: 50 mL clear glass moulded vial with a grey bromobutyl rubber stopper and a yellow or dark blue aluminium flip-off seal.

SEDMEDEX RTU 100 mL: 100 mL clear glass moulded vial with a grey bromobutyl rubber stopper and a yellow or dark blue aluminium flip-off seal.

Pack size: 1, 5 or 10 vials packed in an outer carton.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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Registration numbers

SEDMEDEX RTU 50 mL: 59/2.9/0983

SEDMEDEX RTU 100 mL: 59/2.9/0984

Access to the corresponding Professional Information

Website Address: www.trinitypharma.co.za