

## PATIENT INFORMATION LEAFLET

### SCHEDULING STATUS

S5

### DEXISUN Concentrated solution for intravenous infusion

#### Dexmedetomidine

### Read all of this leaflet carefully before you are given DEXISUN

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

#### 1. What DEXISUN is and what it is used for

The active substance is dexmedetomidine.

Dexmedetomidine belongs to a group of medicines called psycholeptics. They are used for sedation in hospital.

**DEXISUN should not be used outside an Intensive Care Unit setting or surgical operating theatres. There should be continuous monitoring of vital parameters.**

DEXISUN is used:

- For sedation of patients in Intensive Care Unit (ICU) who have undergone surgery and are on a mechanical ventilator.
- For sedation when you receive certain surgical procedures under a local anaesthesia or nerve block or when you are receiving a breathing tube while awake.

## **2. What you need to know before you use DEXISUN:**

### **DEXISUN should not be administered to you:**

- if you are hypersensitive (allergic) to dexmedetomidine or to any other ingredient of DEXISUN.
- if you have any septic conditions (when chemical released in the blood to fight infections trigger inflammation throughout the body)
- 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 low blood pressure
- if you have acute cerebrovascular conditions, which includes conditions that affect the flow of blood through the brain.
- if you are pregnant or breastfeeding your baby (see **Pregnancy and Breastfeeding**).

## Warnings and precautions

Tell your doctor or health care provider before being given the DEXISUN:

Special care should be taken with DEXISUN:

- if you have advanced heart block (your heart beats slowly or skip beats)
- if you have heart conditions where your heart beats slower than normal (bradycardia disorders), pre-existing severe ventricular dysfunction, a heart condition which also includes heart failure, as DEXISUN may decrease blood pressure or heart rate
- if you are elderly, have diabetes, chronic hypertension (high blood pressure) or severe heart disease as DEXISUN decreases sympathetic nervous activity, that is the ability of your nervous system to produce responses such as sweating during increased temperatures and reflex adjustments
- if you have liver or kidney problems
- if you have diabetes
- if you have high blood pressure
- as DEXISUN may have reduce the ability of your eyes to produce tears, your doctor will advise on lubrication of your eyes should this occur
- when used with other sedatives as they might increase the effect of DEXISUN
- When you have diseases that affect the brain as well as nerves found through the human body and spinal cord (severe neurological disorders), as DEXISUN may reduce the flow of blood to the brain
- if you develop unexplained fever, treatment with DEXISUN must be discontinued
- if you are 65 years and older.

## Children and adolescents

The efficacy and safety has not been studied in children under 18 years of age.

### **Other medicines and DEXISUN**

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

DEXISUN may interact with:

- Anaesthetic medicines (e.g. sevoflurane, isoflurane) as DEXISUN may increase their effect
- Medicines that help you sleep or cause sedation (e.g. midazolam, propofol); as they may increase the effect of DEXISUN
- Strong painkillers (e.g. opioids such as morphine, codeine)
- Medicines used to control high blood pressure and those that affect the contraction of your heart
- Beta blockers, which are medicines used to reduce blood pressure may increase the possibility of increased low blood pressure.

### **Pregnancy and breastfeeding:**

The safe use of DEXISUN during pregnancy and breastfeeding has not been determined and therefore you should not receive DEXISUN if you are pregnant or breastfeeding your baby.

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 healthcare provider for advice before receiving DEXISUN.

### **Driving and using machines:**

You should not drive or operate machines or make legal decisions until 24 hours after recovery from surgical procedure in which DEXISUN was used.

### **3. How to receive DEXISUN**

You will not be expected to give yourself DEXISUN. It will be given to you by a person who is qualified to do so. During the administration of DEXISUN, your vital signs (blood pressure, heart rate and oxygen levels) will be monitored.

You should never receive DEXISUN 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 DEXISUN for longer than 24 hours.

#### **Dosage:**

Your doctor will determine the dose of DEXISUN 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.

#### **If you receive more DEXISUN than you should:**

Since DEXISUN will be given to you by a doctor or nurse under carefully controlled conditions, it is unlikely that you will be given too much. If you have received too much DEXISUN, your doctor will manage the overdose.

If you have any further questions on the use of DEXISUN, ask your doctor or pharmacist.

#### **If you forget to use DEXISUN**

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

### **4. Possible side effects**

DEXISUN can have side effects.

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

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

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching.

These are very serious side effects. If you have them, you may have had a serious allergic reaction to DEXISUN. 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:

- change in breathing pattern or stopping breathing
- low or high blood pressure
- a slower than normal heartbeat, reduced heart function
- fast heart rate, irregular heartbeat
- chest pain or heart attack
- yellowing of the skin and eyes, also called jaundice

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

*Frequent:*

- nausea, vomiting, dry mouth
- low oxygen levels in the body tissues
- agitation

- very high temperature (Hyperpyrexia)

*Less frequent:*

- infections or sepsis
- blood problems (such as abnormal clotting, low white or red blood cells)
- a condition where there is too much acid in the body
- thirst
- low or high blood sugar
- anxiety, confusion
- depression, nervousness
- hallucination (seeing something that is not really there)
- convulsion (fits), dizziness, headache
- nerve pain, numbness
- an abnormal sensation (pins and needles) in the fingers hands, toes, or feet
- speech problems
- disturbances in vision
- coughing
- increased saliva
- lung and breathing problems
- stomach pain, diarrhoea
- ulcers
- liver function problems
- kidney function problems
- increased sweating
- muscle weakness
- swelling

- pain
- chills and shivers
- Increased urination

If any of the side effects become serious, or if you notice any side-effects not listed 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 “**6.04 Adverse Drug Reaction 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 DEXISUN.

### **5. How to store DEXISUN**

Store all medicines out of reach of children.

Store at or below 25 °C in the original container.

Do not refrigerate.

Once diluted, the diluted should be used immediately. If not used immediately, the diluted solution may be stored at 2 – 8 °C during the 24 hour “in use” period. Discard any unused diluted solution after 24 hours.

Do not use DEXISUN after the expiry date stated on the vial. The expiry date refers to the last day of that month.

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

### **6. Contents of the pack and other information**

The active substance is dexmedetomidine.

Each 1 ml of DEXISUN concentrated solution contains dexmedetomidine hydrochloride equivalent to 100 micrograms dexmedetomidine.

The other ingredients are:

Sodium chloride and water for injections.

### **What DEXISUN looks like and contents of the pack**

A clear, colourless solution, free from visible extraneous matter.

DEXISUN is packed in a 2 ml tubular, USP type 1 flint glass vial, with a 13 mm Teflon coated grey rubber stopper and a 13 mm pink aluminium flip-off seal, in a outer carton. Each carton contains 1 or 5 vials.

### **Holder of Certificate of Registration**

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### **Access to the corresponding PIL Translation:**

The PIL is available in one other language (afrikaans), a copy is accessible

on the company website: <https://sunpharma.com/south-africa-products/>

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