Dexmedetomidine Sandoz®

Dexmedetomidine (dex-med-e-toh-med-een) hydrochloride

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Dexmedetomidine Sandoz. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Dexmedetomidine Sandoz against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet.
You may need to read it again.

What Dexmedetomidine Sandoz is used for

Intensive Care Sedation
Dexmedetomidine Sandoz can be used as a sedative (calming agent) if adults need to calm or sleepy in the Intensive Care Unit whilst they are being ventilated (on a breathing machine). It may be given as an infusion up to 24 hours.

Procedural Sedation
Dexmedetomidine Sandoz can be given to adults prior to an operation if they are not on a ventilator (breathing machine) if it is required for the procedure or surgery that they be sleepy and calm.

This medicine belongs to a group of medicines called alpha-2-receptor agonists. This medicine works by its action on brain chemicals.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.
Your doctor may have prescribed it for another reason.

Dexmedetomidine Sandoz is only available with a doctor's prescription.

Before you are given Dexmedetomidine Sandoz

When you must not be given it

Do not use Dexmedetomidine Sandoz if you have an allergy to:

- any medicine containing dexmedetomidine hydrochloride
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

This product is not suitable for use in children.
Safety and effectiveness in children younger than 18 years have not been established.

This medicine should not be used after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If you are not sure whether you should be given this medicine, talk to your doctor.

Before you are given it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- heart problems
- high or low blood pressure
- diabetes
- kidney or liver problems

Elderly patients greater than 65 years old may be more prone to the blood pressure lowering effects of Dexmedetomidine Sandoz.

An increased risk of death has been seen for patients 65 years of age and under when using this medicine. This increased risk is seen particularly in patients admitted to the intensive care unit for reasons other than after surgery; who have a more severe disease condition; and who are younger. Your doctor will decide if this medicine is still suitable for you.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.
The active ingredient in Dexmedetomidine Sandoz may affect your developing baby if you take it during pregnancy. It also passes into breast milk and there is a possibility that your baby may be affected. Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you start using Dexmedetomidine Sandoz.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Dexmedetomidine Sandoz may interfere with each other. These include:

- medicines used to produce calmness or to help you sleep, such as sevoflurane, isoflurane, propofol, alfentanil and midazolam
- strong pain relievers

These medicines may be affected by Dexmedetomidine Sandoz or may affect how well it works. You may need different amounts of your medicines, or you may need to use different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to use Dexmedetomidine Sandoz

Dexmedetomidine Sandoz will be given to you by your doctor or nurse in hospital.

How much to use

Your doctor will decide what dose you will receive. This depends on your condition and other factors such as your weight. The dose will be adjusted to keep you at the right depth of sleep or sedation.

How it is given

Dexmedetomidine Sandoz is given by a slow injection (drip) into a vein. Dexmedetomidine Sandoz should only be given by a doctor or nurse.

If you are given too much (overdose)

As Dexmedetomidine Sandoz is given to you under the supervision of your doctor, it is very unlikely that you will receive too much.

Symptoms of an overdose may include extreme drowsiness, confusion, dizziness, weakness or becoming unconscious.

Your doctor has information on how to recognise and treat an overdose. Ask your doctor if you have any concerns.

If you think you or someone else may have been given too much Dexmedetomidine Sandoz, you should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning.
You may need urgent medical attention.

While you are using Dexmedetomidine Sandoz

Things you must do

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.
It may affect other medicines used during surgery.

If you become pregnant while taking this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.
It may interfere with the results of some tests.

Things to be careful of

Be careful driving or operating machinery until you know how Dexmedetomidine Sandoz affects you.
This medicine may cause dizziness, light-headedness, tiredness, drowsiness and therefore affect alertness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous. Ask your doctor when you can return to work involving driving or operating machinery or heavy equipment.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.
Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Dexmedetomidine Sandoz.

This medicine helps most people with sedation, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

If you are over 65 years of age you may have an increased chance of getting side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- dizziness

- light-headedness
- nausea and/or vomiting
- high temperature
- dry mouth
- constipation or diarrhoea
- feelings of agitation, confusion or tiredness
- fluid retention or swelling in the arms or legs
- changes in your blood sugar levels
- increased sweating
- changes to your vision
- reduced or increased urine output or feeling thirsty

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

Tell your doctor as soon as possible if you notice any of the following:

- changes in heart rate including slowing or quickening or heart beat
- shortness of breath, rapid breathing or breathing difficulties
- chest pain
- cough
- wheezing

The above list includes serious side effects that may require medical attention.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- pressure, tightness or pain in your chest or arms that may spread to your neck, jaw or back
- unusual bruising
- overheating of your body that you can't control by normal cooling methods
- excessive thirst, extreme fatigue, lack of energy, confusion, muscle twitching or spasms, restlessness, seizures

The above list includes serious side effects. You may need urgent medical attention or hospitalisation and your medicine may need to be stopped.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Some side effects can only be detected by blood or urine test. Your doctor will monitor your progress.

Other side effects not listed above may also occur in some people.

After using Dexmedetomidine Sandoz

Storage

Dexmedetomidine Sandoz will be stored in the pharmacy or kept in the ward. The injection is kept in a cool dry place where the temperature stays below 25ºC.

Product description

What it looks like

Dexmedetomidine Sandoz is a clear, colourless solution. It is available in 2 mL glass vials.

Ingredients

Dexmedetomidine Sandoz contains 118 mg of dexmedetomidine hydrochloride (equivalent to 100 mcg/mL dexmedetomidine base) as the active ingredient.

It also contains:

- sodium chloride
- water for injections

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Vial stopper is not made with natural rubber latex.

Supplier / Sponsor

Dexmedetomidine Sandoz is supplied by:

Sandoz Pty Ltd
100 Pacific Highway
North Sydney, NSW 2060
Australia
Tel 1800 726 369

Dexmedetomidine Sandoz is available in the following strength:

200 microgram/2 mL

AUST R 288791

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