

Dexmedetomidine Mylan

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

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about Dexmedetomidine Mylan. 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 Mylan against the benefits they expect it will have for you.

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

Keep this leaflet

You may need to read it again.

What Dexmedetomidine Mylan is used for

Intensive Care Sedation

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

Procedural Sedation

Dexmedetomidine Mylan can be given to adults prior to an operation if they are not on a ventilator (breathing machine) and if they are

required to be sleepy and calm for the procedure or surgery performed in a hospital.

This medicine belongs to a group of medicines called alpha-2-receptor agonists. This medicine works by its actions 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 Mylan is only available with a doctor's prescription.

Before you are given Dexmedetomidine Mylan

When you must not use it

Do not use Dexmedetomidine Mylan 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

Do not use this medicine if you are pregnant.

It may affect your developing baby if you use it during pregnancy.

Do not breast-feed if you are given this medicine.

The active ingredient in Dexmedetomidine Mylan passes into breast milk and there is a possibility that your baby may be affected.

Do not give this medicine to a child under the age of 18 years.

Safety and effectiveness in children younger than 18 years have not been established.

Do not use this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, it will be disposed of by the hospital pharmacist.

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:

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

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

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.

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 are given Dexmedetomidine Mylan.

Taking other medicines

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

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

- medicines used to produce calmness or to help you sleep
- strong pain relievers

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

Your doctor and pharmacist have more information on medicines to be careful with or avoid if you are given this medicine whilst in hospital.

How Dexmedetomidine Mylan is given

How this medicine is given

Dexmedetomidine Mylan is given by a slow injection (drip) into a vein. Dexmedetomidine Mylan should only be given by a doctor or nurse in the hospital.

How much is given

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.

What do I do if I am given too much? (overdose)

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

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

If you think you or someone else may have been given too much Dexmedetomidine Mylan, 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.

After you are given Dexmedetomidine Mylan

Your doctor will be able to tell you whether there are any special instructions you should follow after you have been given Dexmedetomidine Mylan.

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 you must not do

Do not take Dexmedetomidine Mylan to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Things to be careful of

Do not drive or operate machinery until you know how Dexmedetomidine Mylan 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 if it involves 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 a chair, 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 after you have been given Dexmedetomidine Mylan.

This medicine helps provide sedation for most people, but it may have unwanted side effects in some 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 list 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 or nurse as soon as possible if you notice any of the following:

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

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 very serious side effects. You may need urgent medical attention or hospitalisation.

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

Other side effects not listed above may also occur in some people. After using Dexmedetomidine Mylan

Storage

Dexmedetomidine Mylan will be stored in the hospital pharmacy or kept on the ward. The injection is kept in a cool dry place where the temperature stays below 25°C.

Product description

What it looks like

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

Ingredients

Dexmedetomidine Mylan contains 118 microgram/mL of dexmedetomidine hydrochloride (equivalent to 100 microgram/mL dexmedetomidine base) as the active ingredient.

It also contains:

- sodium chloride
- water for injections
- nitrogen

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

Supplier / Sponsor

Dexmedetomidine Mylan is supplied by:

Alphapharm Pty Ltd

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.mylan.com.au

Australian registration numbers

Dexmedetomidine Mylan is available in the following strengths:

200 microgram/2 mL -

AUST R 271410

Date of preparation

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