

DEXMEDETOMIDINE ACCORD

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I being given Dexmedetomidine Accord?

Dexmedetomidine Accord contains the active ingredient dexmedetomidine (as hydrochloride). Dexmedetomidine Accord belongs to a group of medicines called alpha-2-receptor agonists. It is used as a sedative (calming agent) if adults need to be calm or sleepy in the Intensive Care Unit whilst they are being ventilated (on a breathing machine). Dexmedetomidine Accord can be given to adults prior to an operation if they are not on a ventilator if it is required for the procedure or surgery that they be sleepy and calm. It works by its actions on brain chemicals.

For more information, see Section [1. Why am I using Dexmedetomidine Accord?](#) in the full CMI.

2. What should I know before I am given Dexmedetomidine Accord?

Do not use if you have ever had an allergic reaction to any medicine containing dexmedetomidine hydrochloride or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I am given Dexmedetomidine Accord?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Dexmedetomidine Accord and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How will I be given Dexmedetomidine Accord?

Dexmedetomidine Accord will be given to you by a doctor or a nurse.

More instructions can be found in Section [4. How will I be given Dexmedetomidine Accord?](#) in the full CMI.

5. What should I know while being given Dexmedetomidine Accord?

Things you should do	<ul style="list-style-type: none">If you are about to have any blood tests, tell your doctor that you are being given this medicine. It may interfere with the results of some tests.
Driving or using machines	<p>Be careful driving or operating machinery until you know how Dexmedetomidine Accord affects you. Dexmedetomidine Accord 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.</p> <p>Ask your doctor when you can return to work involving driving or operating machinery or heavy equipment.</p>

For more information, see Section [5. What should I know while being given Dexmedetomidine Accord?](#) in the full CMI.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

Some of the very serious side effects are:

- 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

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

DEXMEDETOMIDINE ACCORD

Active ingredient(s): *Dexmedetomidine (as hydrochloride)*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Dexmedetomidine Accord. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Dexmedetomidine Accord.**

Where to find information in this leaflet:

- [1. Why am I being given Dexmedetomidine Accord?](#)
- [2. What should I know before I am given Dexmedetomidine Accord?](#)
- [3. What if I am taking other medicines?](#)
- [4. How will I be given Dexmedetomidine Accord?](#)
- [5. What should I know while being given Dexmedetomidine Accord?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I being given Dexmedetomidine Accord?

Dexmedetomidine Accord contains the active ingredient **dexmedetomidine (as hydrochloride)**. This medicine belongs to a group of medicines called alpha-2-receptor agonists. This medicine works by its actions on brain chemical.

Dexmedetomidine Accord can be used as a sedative (calming agent) if adults need to be calm or sleepy in the Intensive Care Unit whilst they are being ventilated (on a breathing machine).

Dexmedetomidine Accord 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.

2. What should I know before I am given Dexmedetomidine Accord?

Warnings

You must not be given Dexmedetomidine Accord if:

- you have an allergy to dexmedetomidine hydrochloride or any of the ingredients listed at the end of this leaflet.

Do not give Dexmedetomidine Accord to a child under the age of 18 years.

Tell your doctor if you have or have had:

- heart problems
- high or low blood pressure
- diabetes
- kidney or liver problems
- allergies to any other medicines, foods, preservatives or dyes

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

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Tell your doctor if you:

- are pregnant, or intend to become pregnant
- are breastfeeding

The active ingredient in Dexmedetomidine Accord may affect your developing baby if you take it during pregnancy.

Dexmedetomidine Accord also passes into breast milk and there is a possibility that the breast-fed baby may be affected.

Your doctor can discuss with you the risks and benefits involved.

3. What if I am taking other medicines?

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

Some medicines and Dexmedetomidine Accord 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 Accord or may affect how well it works. You may need different amounts of your medicine, or you may need to have different medicines. Your doctor or pharmacist will advise you.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Dexmedetomidine Accord.

4. How will I be given Dexmedetomidine Accord?

How much will be given

Your doctor will decide on 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 Dexmedetomidine Accord will be given

Dexmedetomidine Accord is given by a slow injection (drip) into a vein.

It may be given as an infusion for up to 24 hours.

Dexmedetomidine Accord should only be given by a doctor or nurse.

If you receive too much Dexmedetomidine Accord

Since Dexmedetomidine Accord is usually given to you in hospital under the supervision of your doctor, it is very unlikely that you will be given too much of the medicine.

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

If you think that you have been given too much Dexmedetomidine Accord.

You should immediately:

- phone the National Poisons Centre (0800 POISON or 0800 764 766), or
- contact your doctor, nurse or pharmacist.

5. What should I know while being given Dexmedetomidine Accord?

Things you must do

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

Driving or using machines

Be careful driving or operating machinery until you know how Dexmedetomidine Accord affects you.

Dexmedetomidine Accord 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.

Looking after your medicine

The hospital will store Dexmedetomidine Accord under the correct conditions.

6. Are there any side effects?

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

Dexmedetomidine Accord helps provide sedation for most people, 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.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Common side effects

Less serious side effects	What to do
<ul style="list-style-type: none">• 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 urine output or feeling thirsty	Speak to your doctor if you have any of these common side effects and they worry you

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

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">• 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• changes in heart rate including slowing or quickening of heart beat• shortness of breath, rapid breathing or breathing difficulties	Call your doctor straight away

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

Very Serious side effects

Very serious side effects	What to do
<ul style="list-style-type: none">• 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,	Call your doctor immediately or go straight to the Emergency Department at your nearest hospital

Very serious side effects	What to do
confusion, muscle twitching or spasms, restlessness, seizures	

The above list includes very 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 else that may be making you feel unwell.

Other side effects not listed above may occur in some patients.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the New Zealand Pharmacovigilance Centre online at <https://nzphvc.otago.ac.nz/reporting/>. By reporting side effects, you can help provide more information on the safety of this medicine.

7. Product details

This medicine is only available with a doctor's prescription.

What Dexmedetomidine Accord contains

Active ingredient (main ingredient)	dexmedetomidine (as hydrochloride)
Other ingredients (inactive ingredients)	sodium chloride water for Injections

Do not take this medicine if you are allergic to any of these ingredients.

Dexmedetomidine Accord does not contain gluten, sucrose, lactose, tartrazine or any other azo dyes.

What Dexmedetomidine Accord looks like

Dexmedetomidine Accord is a clear, colourless solution. It is available in 2 mL glass vials in packs of 1, 5 and 25.

Not all pack sizes may be marketed.

Who distributes Dexmedetomidine Accord

Pharmacy Retailing (NZ) Limited Trading as Healthcare Logistics
58 Richard Pearse Drive
Airport Oaks
Auckland 2022
New Zealand

This leaflet was prepared on 12 August 2022.