

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 DEXDOR?

DEXDOR contains the active ingredient dexmedetomidine hydrochloride. DEXDOR is used in adult patients who need to be kept calm or sleepy when either:

- on a breathing machine (ventilator) in the Intensive Care Unit (ICU), or
- unaided by a breathing machine before a surgical or other procedure.

For more information, see Section [1. Why am I being given DEXDOR?](#) in the full CMI.

2. What should I know before I am given DEXDOR?

Do not use if you have ever had an allergic reaction to DEXDOR 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 DEXDOR?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with DEXDOR 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 is DEXDOR given?

DEXDOR is diluted with another liquid in an IV bag and given as a 'drip' through a vein (intravenous infusion) by a doctor or nurse. Your doctor or anaesthetist will decide how fast the infusion will be given to keep you at the right depth of sleep or calmness, and how long you need it.

More information can be found in Section [4. How is DEXDOR given?](#) in the full CMI.

5. What should I know while being given DEXDOR?

Things you should do	<ul style="list-style-type: none">• While DEXDOR is only given when you are in the ICU or surgery, some of it may remain in the body for a short time afterwards. Tell your doctor straight away that you have been given DEXDOR before you start a new medicine, undergo further surgery or blood tests since these may be affected by DEXDOR.• Tell your doctor if you find out that you are pregnant.• If you feel dizzy, light-headed or faint when getting out of bed or standing up, do so slowly.
Driving or using machines	<ul style="list-style-type: none">• DEXDOR may cause dizziness, light-headedness, tiredness or drowsiness and may therefore affect alertness in some people. Avoid driving or operating machinery if you experience these symptoms and ask your doctor for advice.
Looking after your medicine	<ul style="list-style-type: none">• Your doctor, anaesthetist and nurse are responsible for storing, preparing, giving and discarding DEXDOR.

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

6. Are there any side effects?

Common side effects such as dizziness, light-headedness, nausea, vomiting, fever, dry mouth, feeling thirsty, constipation, diarrhoea, agitation, confusion, tiredness, swelling, sweating more, blood sugar changes, vision changes and passing less or more urine are usually mild and short-lived. More serious side effects such as heart rate changes, breathing problems, chest pain or tightness, bruising, overheating, excessive thirst, extreme fatigue, lack of energy, restlessness, confusion, muscle twitches and seizures may require urgent medical attention.

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.

DEXDOR®

Active ingredient: *dexmedetomidine hydrochloride*

Consumer Medicine Information (CMI)

This leaflet provides important information about DEXDOR. **You should also speak to your doctor, anaesthetist or pharmacist if you would like further information or if you have any concerns or questions about being given DEXDOR.**

Where to find information in this leaflet:

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

1. Why am I being given DEXDOR?

DEXDOR contains the active ingredient dexmedetomidine hydrochloride. DEXDOR is a sedative (calming agent) for adults who need to be calmed or sleepy when on a breathing machine (ventilator) in the Intensive Care Unit (ICU). DEXDOR may also be given to adults who are not ventilated before a surgical or other procedure.

2. What should I know before I am given DEXDOR?

Warnings

DEXDOR should not be given to you if:

- you are allergic to dexmedetomidine or sodium chloride.
- Always check the ingredients at the end of this leaflet to make sure you can be given this medicine.

Symptoms of an allergic reaction 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.

Check with your doctor if you:

- have any other medical conditions such as heart problems, high or low blood pressure, diabetes, kidney or liver problems.
- take any medicines for any other condition
- elderly patients 65 years or older may be more prone to the blood pressure lowering effects of DEXDOR.

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

Check with your doctor if you are pregnant or intend to become pregnant. Dexmedetomidine may affect your developing baby if given during pregnancy.

Talk to your doctor if you are breastfeeding or intend to breastfeed. Since it also passes into breast milk, it is possible that your baby may be affected.

Your doctor can discuss with you the risks and benefits of being given DEXDOR.

Children and adolescents

Information on the safety of dexmedetomidine in children and adolescents is limited, therefore it is not recommended for use in patients below 18 years of age.

3. What if I am taking other medicines?

Tell your doctor, anaesthetist 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 that help you sleep, calm down or relieve pain such as sevoflurane, isoflurane, propofol, midazolam, alfentanil and opioids may enhance the effects of dexmedetomidine. Your doctor may adjust your dose to achieve the desired level of sleepiness or calmness.

If you are using medicines which lower your blood pressure and heart rate, co-administration with Dexdor may enhance this effect.

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

4. How is DEXDOR given?

How much is given

- DEXDOR is diluted with another liquid, usually sodium chloride solution (saline), in an IV bag and given as a controlled 'drip' through a vein (intravenous infusion) by a doctor or nurse.
- Your doctor or anaesthetist will decide how fast you receive the diluted solution to keep you at the right depth of sleep or calmness while on the breathing machine or during a surgical procedure. This may depend on factors such as your weight, condition and reaction.
- DEXDOR infusion may be given continuously for up to 24 hours, but your doctor or anaesthetist will decide how long you need it.
- Your doctor, anaesthetist and nurses will monitor your condition while you are being given DEXDOR.

If you are given too much DEXDOR

As DEXDOR is given to you under the supervision of a doctor or anaesthetist, it is very unlikely that you will receive too much. However, if DEXDOR is no longer being given but you experience side effects (see Section [6. Are there any side effects?](#)), tell your doctor. You may need urgent medical attention.

If you have serious side effects after already leaving the ICU or surgery, 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.

5. What should I know while being given DEXDOR?

Things you should do

While DEXDOR is only given when you are in the ICU or are undergoing a surgical or other procedure, some of the drug may remain in your body for a short time afterwards.

Tell your doctor straight away that you have been or are being given DEXDOR if you:

- Are about to be started on any new medicine
- Are going into surgery for another procedure, as it may affect other medicines used during surgery
- Are about to have any blood tests, as it may interfere with the results
- Find out that you are pregnant.

Getting out of bed or standing up

If you feel light-headed, dizzy or faint when getting out of bed or standing up, do so slowly so that your body can get used to the changes in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how DEXDOR has affected you.

DEXDOR may cause dizziness, light-headedness, tiredness or drowsiness and may therefore affect alertness in some people. If you experience any of these conditions, do not drive, operate machinery or do anything else that could be dangerous.

Ask your doctor for advice on when you can resume these activities.

Looking after your medicine

DEXDOR is stored in the hospital pharmacy or kept on the ICU ward where the temperature stays below 25°C. Your doctor, anaesthetist or nurse is responsible for storing, preparing and giving the infusion solution, and discarding any unused solution.

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.

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

Less serious 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• agitation, confusion or tiredness• swelling in the arms or legs (fluid retention)• changes in blood sugar levels• increased sweating• changes to vision• changes to passing urine• feeling thirsty	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p> <p>These are usually mild and short-lived.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">• changes in heart rate including slowing or quickening of heartbeat• wheezing, shortness of breath, rapid breathing or breathing difficulties• pressure, tightness or pain in the chest or arms that may spread to the neck, jaw or back• unusual bruising• overheating of your body that you can't cool by usual methods• excessive thirst, extreme fatigue, lack of energy, confusion, muscle twitching or spasms, restlessness, seizures	<p>Tell your doctor or nurse straight away, or if you have already left the ICU or surgery, go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Tell your doctor if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

7. Product details

This medicine is only given under a doctor's supervision in a hospital or surgery.

What DEXDOR contains

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

DEXDOR must not be given to you if you are allergic to any of these ingredients.

What DEXDOR looks like

DEXDOR is a clear, colourless concentrated solution. It is available in:

- 2 mL clear glass ampoules containing 200 micrograms dexmedetomidine each in packs of 5 or 25 ampoules per carton (AUST R 379412),
- 4 mL clear glass vials containing 400 micrograms dexmedetomidine each in packs of 4 vials per carton (AUST R 379411), and
- 10 mL clear glass vials containing 1000 micrograms dexmedetomidine each in packs of 4 vials per carton (AUST R 379410).

Who distributes DEXDOR

Orion Pharma (Aus) Pty Limited
Level 24, Tower 3, 300 Barangaroo Avenue
Sydney NSW 2000, Australia
Telephone: 1800 861 913

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