

# DEXMEDETOMIDINE BAXTER READY TO USE

## 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 using DEXMEDETOMIDINE BAXTER READY TO USE?

DEXMEDETOMIDINE BAXTER READY TO USE contains the active ingredient Dexmedetomidine (as hydrochloride).

#### ICU Sedation

DEXMEDETOMIDINE BAXTER READY TO USE can be used for sedation of initially intubated patients during treatment in an intensive care setting. The use of DEXMEDETOMIDINE BAXTER READY TO USE by continuous infusion in these patients should not exceed 24 hours.

#### Procedural Sedation

DEXMEDETOMIDINE BAXTER READY TO USE can be used for sedation of non-intubated patients prior to and/or during surgical and other procedures.

For more information, see Section [1. Why am I using DEXMEDETOMIDINE BAXTER READY TO USE?](#) in the full CMI.

### 2. What should I know before I use DEXMEDETOMIDINE BAXTER READY TO USE?

Do not use if you have ever had an allergic reaction to 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 use DEXMEDETOMIDINE BAXTER READY TO USE?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with DEXMEDETOMIDINE BAXTER READY TO USE 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 do I use DEXMEDETOMIDINE BAXTER READY 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.
- Dexmedetomidine should be administered only by persons skilled in anaesthetics or in the management of patients in the intensive care setting. Due to the known pharmacological effects, patients should be continuously monitored.
- A controlled infusion device should be used to administer dexmedetomidine.

More instructions can be found in Section [4. How do I use DEXMEDETOMIDINE BAXTER READY TO USE?](#) in the full CMI.

### 5. What should I know while using [DEXMEDETOMIDINE BAXTER READY TO USE]?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Tell any other doctors, dentist and pharmacists who treat you that you are taking this medicine.</li><li>• 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.</li><li>• Tell your doctor if you are pregnant or breastfeeding.</li><li>• Tell your doctor if you are taking any other medications.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not take Dexmedetomidine concentrated injection to treat any other complaints unless your doctor tells you to.</li><li>• Do not give your medicine to anyone else, even if they have the same condition as you.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• 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.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• DEXMEDETOMIDINE BAXTER READY TO USE will be stored in the hospital pharmacy or on the hospital ward in original container where the temperature stays below 25°C.</li></ul>

For more information, see Section [5. What should I know while using DEXMEDETOMIDINE BAXTER READY TO USE?](#) in the full CMI.

### 6. Are there any side effects?

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking DEXMEDETOMIDINE BAXTER READY TO USE.

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.

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 BAXTER READY TO USE

**Active ingredient(s):** *Dexmedetomidine (dex-med-e-toh-med-een) hydrochloride*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using DEXMEDETOMIDINE BAXTER READY TO USE. **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 BAXTER READY TO USE.**

**Where to find information in this leaflet:**

1. [Why am I using DEXMEDETOMIDINE BAXTER READY TO USE?](#)
2. [What should I know before I use DEXMEDETOMIDINE BAXTER READY TO USE?](#)
3. [What if I am taking other medicines?](#)
4. [How do I use DEXMEDETOMIDINE BAXTER READY TO USE?](#)
5. [What should I know while using DEXMEDETOMIDINE BAXTER READY TO USE?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

## 1. Why am I using DEXMEDETOMIDINE BAXTER READY TO USE?

DEXMEDETOMIDINE BAXTER READY TO USE contains the active ingredient **Dexmedetomidine (as hydrochloride)**. Dexmedetomidine is a relatively selective alpha2-adrenoreceptor agonist with a broad range of pharmacologic properties.

### Intensive Care Unit (ICU) Sedation

DEXMEDETOMIDINE BAXTER READY TO USE can be used for sedation of initially intubated patients during treatment in an intensive care setting. The use of DEXMEDETOMIDINE BAXTER READY TO USE by continuous infusion in these patients should not exceed 24 hours.

### Procedural Sedation

DEXMEDETOMIDINE BAXTER READY TO USE can be used for sedation of non-intubated patients prior to and/or during surgical and other procedures.

## 2. What should I know before I use DEXMEDETOMIDINE BAXTER READY TO USE?

### Warnings

**Do not use DEXMEDETOMIDINE BAXTER READY TO USE if:**

- You are allergic to Dexmedetomidine hydrochloride, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

- 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 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 take 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, return it to your pharmacist for disposal.

### Check with your doctor if you:

Have allergies to any other medicines, foods, preservatives or dyes.

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 BAXTER READY TO USE.

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.

## 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 may interfere with DEXMEDETOMIDINE BAXTER READY TO USE and affect how it works.**

- 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 BAXTER READY TO USE 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 while taking this medicine.

#### 4. How do I use DEXMEDETOMIDINE BAXTER READY TO USE?

##### 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.
- DEXMEDETOMIDINE BAXTER READY TO USE is given by a slow injection (drip) into a vein.
- DEXMEDETOMIDINE BAXTER READY TO USE should only be given by a doctor or nurse.

##### If you use too much DEXMEDETOMIDINE BAXTER READY TO USE

As DEXMEDETOMIDINE BAXTER READY TO USE 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. If you think that you have used too much DEXMEDETOMIDINE BAXTER READY TO USE, you may need urgent medical attention.

##### 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.

**You should do this even if there are no signs of discomfort or poisoning.**

#### 5. What should I know while using DEXMEDETOMIDINE BAXTER READY TO USE?

##### Things you should 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 should not do

**Do not take DEXMEDETOMIDINE BAXTER READY TO USE 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.**

##### Driving or using machines

**Be careful before you drive or use any machines or tools until you know how DEXMEDETOMIDINE BAXTER READY TO USE 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.

##### Looking after your medicine

- DEXMEDETOMIDINE BAXTER READY TO USE will be stored in the hospital pharmacy or on the hospital ward in original container where the temperature stays below 25°C.

##### Getting rid of any unwanted medicine

Your doctor, nurse or pharmacist will dispose of any leftover medicine.

#### 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 or pharmacist 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"> <li>• dizziness</li> <li>• light-headedness</li> <li>• nausea and/or vomiting</li> <li>• high temperature</li> <li>• dry mouth</li> <li>• constipation or diarrhoea</li> <li>• feelings of agitation, confusion or tiredness</li> <li>• fluid retention or swelling in the arms or legs</li> <li>• changes in your blood sugar levels</li> <li>• increased sweating</li> <li>• changes to your vision</li> <li>• reduced or increased urine output or feeling thirsty</li> </ul>	<p><b>If you are over 65 years of age you may have an increased chance of getting side effects.</b></p> <p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

## Serious side effects

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

**Tell your doctor or pharmacist 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](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

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

### What DEXMEDETOMIDINE BAXTER READY TO USE contains

<b>Active ingredient (main ingredient)</b>	Dexmedetomidine hydrochloride 4.72 micrograms/mL (equivalent to 4 micrograms/mL dexmedetomidine base)
<b>Other ingredients (inactive ingredients)</b>	Sodium chloride Sodium acetate trihydrate Glacial acetic acid Water for injections
<b>Potential allergens</b>	This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

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

### What DEXMEDETOMIDINE BAXTER READY TO USE looks like

DEXMEDETOMIDINE BAXTER READY TO USE dexmedetomidine hydrochloride 4 micrograms/mL is a clear, colourless, isotonic solution with a pH of 4.5 to 5.5. It is presented in 50 mL (AUST R 393053) and 100 mL (AUST R 393052) GALAXY bag containers.

### Who distributes DEXMEDETOMIDINE BAXTER READY TO USE

Baxter Healthcare Pty Ltd  
1 Baxter Drive  
Old Toongabbie  
NSW 2146, Australia

This leaflet was prepared in July 2022.