

Dexmedetomidine Kabi

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 Kabi?

Dexmedetomidine Kabi contains the active ingredient dexmedetomidine hydrochloride. Dexmedetomidine Kabi is used for: [Intensive Care Sedation](#)

Dexmedetomidine Kabi 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). It may be given as an infusion up to 24 hours.

[Procedural Sedation](#)

Dexmedetomidine Kabi 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.

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

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

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 am given Dexmedetomidine Kabi?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Dexmedetomidine Kabi and affect how it works. These include:

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

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

4. How is Dexmedetomidine Kabi given?

Dexmedetomidine Kabi 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 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 instructions can be found in Section [4. How is Dexmedetomidine Kabi given?](#) in the full CMI.

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

Things you should do	<ul style="list-style-type: none">• While Dexmedetomidine Kabi 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 Dexmedetomidine Kabi before you start a new medicine, undergo further surgery or blood tests since these may be affected by Dexmedetomidine Kabi.• Tell your doctor if you find out that you are pregnant.
Driving or using machines	<ul style="list-style-type: none">• Be careful driving or operating machinery until you know how Dexmedetomidine Kabi affects you.

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

6. Are there any side effects?

All medicines can have side effects. Sometimes they are serious, most of the time they are not. However, some side effects may need medical attention and they may include:

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

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 Kabi (dex-med-e-toh-med-een)

Active ingredient(s): *Dexmedetomidine hydrochloride*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I being given Dexmedetomidine Kabi?

Dexmedetomidine Kabi contains the active ingredient dexmedetomidine hydrochloride.

Dexmedetomidine Kabi is used for:

Intensive Care Sedation

Dexmedetomidine Kabi 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). It may be given as an infusion up to 24 hours.

Procedural Sedation

Dexmedetomidine Kabi 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 actions on brain chemicals.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

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

Warnings

Do not use Dexmedetomidine Kabi 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

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Dexmedetomidine may affect your developing baby if given during pregnancy. 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 Dexmedetomidine Kabi.

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.

Before you start

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.

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

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 Kabi 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 Kabi or may affect how well it works. Your doctor may adjust your dose to achieve the desired level of sleepiness

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

4. How is Dexmedetomidine Kabi given?

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.

How it is given

Dexmedetomidine Kabi is diluted with another liquid, usually sodium chloride solution (saline), in a bag and is given as a controlled 'drip' through a vein (intravenous infusion). Dexmedetomidine Kabi should only be given by a doctor or nurse.

If you are given too much

As Dexmedetomidine Kabi 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.

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

Things you must do

Tell any other doctors, dentists, and pharmacists who treat you that you have been given this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you have been given this medicine.

It may affect other medicines used during surgery.

If you become pregnant after being given this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you have been given this medicine.

It may interfere with the results of some tests.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Dexmedetomidine Kabi 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.

Looking after your medicine

Dexmedetomidine Kabi will be stored in the pharmacy or kept on the ward. They are kept in a cool dry place where the temperature stays below 25°C.

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.

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.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">dizzinesslight-headednessnausea and/or vomitinghigh temperaturedry mouthconstipation or diarrhoeafeelings of agitation, confusion or tirednessfluid retention or swelling in the arms or legschanges in your blood sugar levelsincreased sweatingchanges to your visionreduced or increased urine output or feeling thirsty	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">changes in heart rate including slowing or quickening of heart beatshortness of breath, rapid breathing or breathing difficultiespressure, tightness or pain in your chest or arms that may spread to your neck, jaw or backunusual bruisingoverheating of your body that you can't control by normal cooling methods	Tell your doctor or nurse straight away, or if you have already left the hospital or surgery, go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

<ul style="list-style-type: none"> excessive thirst, extreme fatigue, lack of energy, confusion, muscle twitching or spasms, restlessness, seizures 	
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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. 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 Kabi contains

Active ingredient (main ingredient)	118 micrograms/mL of dexmedetomidine hydrochloride (equivalent to 100 micrograms/mL dexmedetomidine base)
Other ingredients (inactive ingredients)	Sodium chloride Water for injections
Potential allergens	None

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

What Dexmedetomidine Kabi looks like

Dexmedetomidine Kabi is a clear colourless solution.

The product is supplied in glass vial (with filling volumes 2mL, 4mL and 10mL).

AUST R 379591 200 micrograms/2 mL

AUST R 379590 400 micrograms/4 mL

AUST R 379592 1000 micrograms/10 mL

Who distributes Dexmedetomidine Kabi

Fresenius Kabi Australia Pty Limited

Level 2, 2 Woodland Way Mount Kuring-gai NSW 2080

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This leaflet was prepared in January 2023.