

DEXMEDETOMIDINE VIATRIS

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

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 VIATRIS?

DEXMEDETOMIDINE VIATRIS contains the active ingredient dexmedetomidine hydrochloride. DEXMEDETOMIDINE VIATRIS is used for:

Intensive Care Sedation

DEXMEDETOMIDINE VIATRIS 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 VIATRIS 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.

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

2. What should I know before I am given DEXMEDETOMIDINE VIATRIS?

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 VIATRIS?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with DEXMEDETOMIDINE VIATRIS and affect how it works. These include medicines used to produce calmness or to help you sleep and 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 VIATRIS given?

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

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

5. What should I know while being given DEXMEDETOMIDINE VIATRIS?

Things you should do	• If you are going to have surgery, tell the surgeon or anaesthetist that you were given DEXMEDETOMIDINE VIATRIS. It may affect other medicines used during surgery. • Tell your doctor if you find out that you are pregnant. • If you are about to have any blood tests, tell your doctor that you have been given this medicine.
Driving or using machines	• Do not drive or operate machinery until you know how DEXMEDETOMIDINE VIATRIS affects you.

For more information, see Section [5. What should I know while using DEXMEDETOMIDINE VIATRIS?](#) 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. You may need medical attention if you get some of the side effects and they may include Changes in heart rate including slowing or quickening of heartbeat, shortness of breath, rapid breathing or breathing difficulties, cough, wheezing and chest pain. 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 VIATRIS

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

Consumer Medicine Information (CMI)

This leaflet provides important information about using DEXMEDETOMIDINE VIATRIS. **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 VIATRIS.**

Where to find information in this leaflet:

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

1. Why am I being given DEXMEDETOMIDINE VIATRIS?

DEXMEDETOMIDINE VIATRIS contains the active ingredient dexmedetomidine hydrochloride.

This medicine belongs to a group of medicines called alpha-2- receptor agonists. This medicine works by its actions on brain chemicals

DEXMEDETOMIDINE VIATRIS is used for:

Intensive Care Sedation

DEXMEDETOMIDINE VIATRIS 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 VIATRIS 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.

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 VIATRIS is only available with a doctor's prescription.

2. What should I know before I am given DEXMEDETOMIDINE VIATRIS?

Warnings

Do not use DEXMEDETOMIDINE VIATRIS 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.

Check with your doctor if you:

- **allergies to any other medicines, foods, preservatives or dyes.**
- have any other medical conditions such as:
 - o diabetes
 - o kidney or liver problems
 - o heart problems
 - o high or low blood pressure
- take any medicines for any other condition
- Elderly patients greater than 65 years old may be more prone to the blood pressure lowering effects of DEXMEDETOMIDINE VIATRIS.

An increased risk of death has been seen for patients 65 years of age and under when using this medicine. This increased risk is seen particularly in patients admitted to the intensive care unit for reasons other than after surgery; who have a more severe disease condition; and who are younger. Your doctor will decide if this medicine is still suitable for you.

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.

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

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

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

If you have not told your doctor about any of the above, tell him/her before you are given DEXMEDETOMIDINE VIATRIS.

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 VIATRIS 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 VIATRIS 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.

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 VIATRIS.

4. How is DEXMEDETOMIDINE VIATRIS 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 VIATRIS is given by a slow injection (drip) into a vein. DEXMEDETOMIDINE VIATRIS should only be given by a doctor or nurse in the hospital.

If you use too much DEXMEDETOMIDINE VIATRIS

As DEXMEDETOMIDINE VIATRIS 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.

Your doctor has information on how to recognise and treat an overdose. Ask your doctor if you have any concerns.

If you think you or someone else may have been given too much DEXMEDETOMIDINE VIATRIS, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, 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 being given DEXMEDETOMIDINE VIATRIS?

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

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 use DEXMEDETOMIDINE VIATRIS 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 VIATRIS 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.

Looking after your medicine

DEXMEDETOMIDINE VIATRIS 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.

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.

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.

This medicine helps provide sedation for most people, but it may have unwanted side effects in some people.

Do not be alarmed by the following list 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
- 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	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
- changes in heart rate including slowing or quickening of heart beat - shortness of breath, rapid breathing or breathing difficulties - cough - wheezing - chest pain - 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	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.

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

Some side effects can only be detected by blood or urine test. Your doctor will monitor your progress.

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 VIATRIS contains

Active ingredient (main ingredient)	DEXMEDETOMIDINE VIATRIS contains 118 microgram/mL of dexmedetomidine hydrochloride (equivalent to 100 microgram/mL dexmedetomidine base) as the active ingredient.
Other ingredients (inactive ingredients)	sodium chloride water for injections nitrogen

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

What DEXMEDETOMIDINE VIATRIS looks like

DEXMEDETOMIDINE VIATRIS is a clear, colourless solution. It is available in 2 mL glass vials.

200 microgram/2 mL - AUST R 271410.

Who distributes DEXMEDETOMIDINE VIATRIS

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

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