DEXMEDETOMIDINE VIATRIS

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 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 can also 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?

You will not be given DEXMEDETOMIDINE VIATRIS 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 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	• Remind any doctor, surgeon, anesthetist or dentist you visit that you have been given DEXMEDETOMIDINE VIATRIS. This medicine may affect other medicines used during surgery. • If you are pregnant or unsure if you are pregnant, tell your doctor immediately. • If you are about to have any blood tests, tell your doctor that you have been given this medicine.
Things you should not do	• You should not be given DEXMEDETOMIDINE VIATRIS if you

	have ever had an allergic reaction to DEXMEDETOMIDINE VIATRIS, or any of the ingredients listed at the end of the CMI.
Driving or using machines	• Do not drive or operate machinery until you know how DEXMEDETOMIDINE VIATRIS affects you.
Looking after your medicine	• DEXMEDETOMIDINE VIATRIS is stored in the pharmacy or kept on the hospital ward at temperature below 25°C.

For more information, see Section 5. What should I know while being given DEXMEDETOMIDINE VIATRIS? in the full CMI.

6. Are there any side effects?

Side effects of this medicine may include: headache; dizziness; light-headedness; nausea; vomiting; high temperature; feeling chills; dry mouth; constipation; diarrhoea; agitation; confusion; depression; anxiety; hallucination; trouble with speech / understanding speech; fainting; tiredness; fluid retention (swelling in arms / legs); increased sweating; vision change; dry eyes; clammy skin; reduced or increased urine

output; thirst; slowing or quickening of heart beat or palpitations; shortness of breath, rapid breathing or breathing difficulties; wheezing; tightness or pain in chest or arms that may spread to your neck, jaw or back; loud snoring, gasping for air during sleep; jaundice; unusual bruising; extreme fatigue; 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 VIATRIS

Active ingredient: Dexmedetomidine (as 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.

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.

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.

Check with your doctor if you:

- have allergies to any other medicines, foods, preservatives or dyes.
- have any other medical conditions such as:
  - diabetes
  - kidney or liver problems
  - heart problems
  - high or low blood pressure
- take any medicines for any other condition.
- are over 65 years of age as 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 than 65. 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 unsure 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.

Use in Children

Do not give this medicine to a child under the age of 18 years.

Safety and effectiveness of DEXMEDETOMIDINE VIATRIS in children younger than 18 years have not been established.

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
- medicines used to control blood pressure such as beta-blockers

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 they 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 DEXMEDETOMIDINE VIATRIS 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, 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 have been given too much DEXMEDETOMIDINE VIATRIS or if you experience any side effects, tell your doctor immediately.

5. What should I know 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 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.
- Tell your doctor if you are pregnant.
- 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 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.

Things to be careful of

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.

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
• headache • dizziness or light-headedness • looking pale • feeling chills • nausea and/or vomiting • high temperature	**Speak to your doctor if you have any of these less serious side effects and they worry you. They are usually mild and short-lived.**

Less serious side effects	What to do
• dry mouth • constipation or diarrhoea • feelings of agitation, anxiety, confusion, hallucination, depression, or tiredness • trouble with speech, or understanding speech • pain, tingling or numbness • fluid retention or swelling in the arms or legs • changes in your blood sugar levels • increased sweating • changes to your vision / blurred vision • reduced or increased urine output or feeling thirsty • lack of appetite	

Serious side effects

Serious side effects	What to do
• dry eyes, that if left untreated may cause damage • clammy skin • severe headache • changes in heart rate including slowing or quickening of heart beat or palpitations • shortness of breath, rapid breathing, wheezing or breathing difficulties • fainting • loud snoring, gasping for air during sleep • difficulty staying asleep • cough • 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	**Tell your doctor straight away if you notice any of these serious side effects.**

Serious side effects	What to do
• excessive thirst, extreme fatigue, lack of energy, confusion, muscle twitching or spasms, restlessness, seizures • jaundice or a yellowing of the skin or eyeballs, often with fever, fatigue, loss of appetite, dark coloured urine or light-coloured bowel movements	

Some of these side effects (for example blood abnormalities) can only be found when your doctor does tests to check your progress.

The above list includes serious side effects. You may need urgent medical attention 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 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)**	118 microgram/mL of dexmedetomidine hydrochloride (equivalent to 100 microgram/mL dexmedetomidine base)
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 (200 microgram/2 mL - AUST R 271410) is a clear, colourless solution. It is available in 3 mL glass vials.

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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