

PRECEDEX® / PRECEDEX® 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 being treated with PRECEDEX?

PRECEDEX contains the active ingredient dexmedetomidine hydrochloride. PRECEDEX 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) 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 treated with PRECEDEX?](#) in the full CMI.

2. What should I know before treatment with PRECEDEX?

You will not be given PRECEDEX if you have ever had an allergic reaction to PRECEDEX 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 treatment with PRECEDEX?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with PRECEDEX 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 PRECEDEX given?

PRECEDEX is given by a slow injection (drip) into a vein by a doctor or nurse. 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 PRECEDEX given?](#) in the full CMI.

5. What should I know during treating with PRECEDEX?

| | |
|------------------------------------|---|
| Things you should do | <ul style="list-style-type: none">• Remind any doctor or dentist you visit that you have been given PRECEDEX.• 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 are using this medicine. |
| Things you should not do | <ul style="list-style-type: none">• You should not be given PRECEDEX if you have ever had an allergic reaction to PRECEDEX, or any of the ingredients listed at the end of the CMI. |
| Looking after your medicine | <ul style="list-style-type: none">• PRECEDEX 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 during treatment with PRECEDEX?](#) 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.

PRECEDEX® / PRECEDEX® READY TO USE

dexmedetomidine hydrochloride

Consumer Medicine Information (CMI)

This leaflet provides important information about using PRECEDEX. **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 PRECEDEX.**

Where to find information in this leaflet:

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

1. Why am I being treated with PRECEDEX?

PRECEDEX contains the active ingredient dexmedetomidine hydrochloride. It belongs to a group of medicines called alpha-2-receptor agonists. It works by its actions on brain chemicals.

Intensive Care Sedation

PRECEDEX 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 (drip) up to 24 hours.

Procedural Sedation

PRECEDEX 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.

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 treatment with PRECEDEX?

Warnings

Do not use PRECEDEX if:

- you are allergic to dexmedetomidine hydrochloride. 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:

- 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 PRECEDEX.

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

Tell your doctor if you are pregnant or unsure if you are pregnant.

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

The active ingredient in PRECEDEX may affect your developing baby if you take it during pregnancy.

It also passes into breast milk and there is a possibility that your baby may be affected.

Your doctor can discuss with you the risks and benefits involved.

Use in children

The safety and effectiveness of PRECEDEX 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 PRECEDEX may interfere with each other. These include:

- medicines used to produce calmness or to help you sleep during surgery, 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 PRECEDEX 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.

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

4. How is PRECEDEX given?

How much to use

Your doctor will decide what dose you will receive. This depends on the reason for use and other factors. The dose will be adjusted to keep you at the right depth of sleep or sedation.

How PRECEDEX is given

PRECEDEX is given by a slow injection (drip) into a vein. PRECEDEX should only be given by a doctor or nurse.

If you use too much PRECEDEX

As PRECEDEX 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 you have been given too much PRECEDEX or if you experience any side effects tell your doctor immediately.

5. What should I know during treatment with PRECEDEX?

Things you should do

- Tell your doctor if you are pregnant.
- 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 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.

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 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.

Drinking alcohol

No information is available.

Looking after your medicine

PRECEDEX is stored in the pharmacy or kept on the hospital ward.

Getting rid of any unwanted medicine

The hospital staff will dispose of any leftover PRECEDEX.

6. Are there any side effects?

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are being given PRECEDEX.

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.

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">● headache● dizziness or light-headedness● looking pale● feeling chills● nausea and/or vomiting● high temperature● dry mouth● constipation or diarrhoea● feelings of agitation, anxiety, confusion, hallucination, depression or tiredness | <p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p> |

| Less serious side effects | What to do |
|--|-------------------|
| <ul style="list-style-type: none"> ● 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 ● lack of appetite. | |

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

Serious side effects

| Serious side effects | What to do |
|--|---|
| <ul style="list-style-type: none"> ● dry eyes, that if left untreated may cause damage ● clammy skin ● severe headache ● slowing or quickening of heart beat or palpitations | <p>Tell your doctor straight away if you notice any of these serious side effects.</p> |

| Serious side effects | What to do |
|---|-------------------|
| <ul style="list-style-type: none"> ● shortness of breath, rapid breathing, wheezing or breathing difficulties ● fainting ● loud snoring, gasping for air during sleep ● difficulty staying asleep ● 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 ● 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 or hospitalisation, and your medicine may need to be stopped.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also 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 PRECEDEX contains

| | |
|---|---|
| Active ingredient (main ingredient) | dexmedetomidine hydrochloride |
| Other ingredients (inactive ingredients) | sodium chloride water for injections |

Do not take this medicine if you are allergic to dexmedetomidine hydrochloride.

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

What PRECEDEX looks like

PRECEDEX (100 micrograms/mL) - is a clear, colourless solution. It is available in 2 mL glass vials.

AUST R 81323

PRECEDEX READY TO USE (4 micrograms/mL) - is a clear, colourless solution. It is available in 20 mL glass vials, and 50 mL or 100 mL glass bottles, as follows:

- 80 micrograms/20 mL, AUST R 234022
- 200 micrograms/50 mL, AUST R 234023
- 400 micrograms/100 mL, AUST R 234024

Who distributes PRECEDEX

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

www.pfizermedicalinformation.com.au

This leaflet was prepared in July 2024.

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