



PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER
DEXMEDETOMIDINE INJECTION
Dexmedetomidine Hydrochloride 100mcg/ml

Read this leaflet carefully before you start taking this medicine.

- If you have any further questions, ask your health care provider.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please inform your health care provider.

In this leaflet:

1. What Dexmedetomidine Injection is and what it is used for
2. What you need to know before you use Dexmedetomidine Injection
3. How to use Dexmedetomidine Injection
4. Possible side effects
5. How to store Dexmedetomidine Injection
6. Contents of the pack and other information

1. WHAT DEXMEDETOMIDINE INJECTION IS AND WHAT IT IS USED FOR

Dexmedetomidine injection is used to provide sedation (a state of calm, drowsiness, or sleep) for adult patients in hospital intensive care settings or awake sedation during different diagnostic or surgical procedures.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE DEXMEDETOMIDINE INJECTION

Do not take Dexmedetomidine Injection:

- If you are allergic to Dexmedetomidine Hydrochloride or any of the other ingredients of this medicine
- If you have some disorders of heart rhythm (heart block grade 2 or 3).
- If you have very low blood pressure which does not respond to treatment.
- If you have recently had a stroke or other serious condition affecting blood supply to the brain

Warnings and precautions

Before you are given this medicine, tell your doctor or nurse if any of the following apply as Dexmedetomidine Hydrochloride should be used cautiously:

- If you have an abnormally slow heart rate (either due to illness or high levels of physical fitness) as it may increase the risk for cardiac arrest
- If you have low blood pressure
- If you have low blood volume, for example after bleeding.
- If you have certain heart disorders
- If you are elderly
- If you have a neurological disorder (for instance head or spinal cord injury or stroke)
- If you have severe liver problems
- If you have ever developed a serious fever after some medicines, especially anaesthetics



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An increased risk of mortality has been observed in patients 65 years of age and younger when using this medication, especially in patients admitted to the intensive care unit for reasons other than postoperative care, with more severe illness on admission to the intensive care unit and with a younger age. The doctor will decide if this medicine is still suitable for you. The doctor will consider the benefits and risks of this medicine for you, in comparison with treatment with other sedatives.

Other medicines and Dexmedetomidine Hydrochloride

Tell your doctor or nurse if you are taking, have recently taken or might take any other medicine.

The following medicines may enhance the effect of Dexmedetomidine Hydrochloride

- Medicines that help you sleep or cause sedation (e.g. Midazolam, propofol)
- Strong pain medicines (e.g. Opioids such as morphine, codeine)
- Anaesthetic medicines (e.g. sevoflurane, isoflurane)

If you are using medicines which lower your blood pressure and heart rate, co-administration with Dexmedetomidine Hydrochloride may enhance this effect. Dexmedetomidine Hydrochloride should not be used with medicines that cause temporary paralysis.

Pregnancy, breast-feeding and fertility.

Dexmedetomidine Hydrochloride should not be used during pregnancy or breast-feeding unless clearly necessary.

Ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Dexmedetomidine Hydrochloride has a major impact on the ability to drive and use machines. After you have been given Dexmedetomidine Hydrochloride you must not drive, operate machinery, or work in dangerous situations. Ask your doctor when you can start doing these activities again and when you can go back to this kind of work.

3. HOW TO USE DEXMEDETOMIDINE INJECTION

Hospital intensive care

Dexmedetomidine Hydrochloride is administered to you by a doctor or nurse in hospital intensive care.

Procedural sedation/awake sedation

Dexmedetomidine Hydrochloride is administered to you by a doctor or nurse prior to and/or during diagnostic or surgical procedures requiring sedation, i.e. procedural/awake sedation. Your doctor will decide on a suitable dose for you. The amount of Dexmedetomidine Hydrochloride depends on your age, size, general condition of health, the level of sedation needed and how you respond to the medicine.



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Your doctor may change your dose if needed and will monitor your heart and blood pressure during the treatment.

After sedation/wake-up

- The doctor will keep you under medical supervision for some hours after the sedation to make sure that you feel well.
- You should not go home unaccompanied.
- Medicines to help you sleep, cause sedation or strong painkillers may not be appropriate for some time after you have been given Dexmedetomidine Hydrochloride. Talk to your doctor about the use of these medicines and about the use of alcohol.

If you have been given more Dexmedetomidine Hydrochloride than you should

If you are given too much Dexmedetomidine Hydrochloride, your blood pressure may go up or down, your heartbeat may slow down, you may breathe more slowly, and you may feel drowsier. Your doctor will know how to treat you based on your condition.

If you have any further questions on the use of this medicine, ask your doctor.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them. These effects are normally mild or moderate and often disappear after a short time.

Very common (affects more than 1 user in 10)

- Slow heart rate
- Low or high blood pressure.
- Change in breathing pattern or stopping breathing.

Common (affects 1 to 10 users in 100)

- Chest pain or heart attack
- Fast heart rate
- Low or high blood sugar
- Nausea, vomiting or dry mouth
- Restlessness
- Symptoms after stopping the medicine
- High temperature

Uncommon (affects 1 to 10 users in 1,000)

- A condition where there is too much acid in the body
- Low albumin level in blood
- Shortness of breath
- Hallucinations
- Reduced heart function, cardiac arrest.



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- The medicine is not effective enough.
- Swelling of the stomach
- Thirst

Not known (frequency cannot be estimated from available data)

Large amount of urine and excessive thirst – may be symptoms of a hormonal disorder called diabetes insipidus. Contact a doctor if these occur.

Reporting of side effects

If you get any side effect, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

5. HOW TO STORE DEXMEDETOMIDINE INJECTION

- Keep this medicine out of the sight and reach of children.
- Store below 30°C
- Do not use Dexmedetomidine Injection after the expiry date which is stated on the carton and label after 'EXP'. The expiry date refers to the last day of that month.

6. FURTHER INFORMATION.

What DEXMEDETOMIDINE INJECTION contains

Each ml of Dexmedetomidine Injection contains 100mcg of Dexmedetomidine Hydrochloride

What DEXMEDETOMIDINE INJECTION looks like and contents of the pack

Clear transparent liquid in 10x2ml ampoules packed in an inner carton

SUPPLIER AND MANUFACTURER

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