Package leaflet: Information for the user
Dexmedetomidine 4 micrograms/ml solution for infusion
dexmedetomidine

Read all of this leaflet carefully before you are given this medicine because it contains important Information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Dexmedetomidine is and what it is used for

Dexmedetomidine contains an active substance called dexmedetomidine which belongs to a medicine group called sedatives. It 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 are given Dexmedetomidine:

You must not be given Dexmedetomidine:
- if you are allergic to dexmedetomidine or any of the other ingredients of this medicine (listed in section 6).
- 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 have this medicine, tell your doctor or nurse if any of the following apply as Dexmedetomidine 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

This medicine may cause large amount of urine and excessive thirst, contact a doctor if these side effects occur. See section 4 for more information.

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 care unit intensive 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
Tell your doctor or nurse if you are taking, have recently taken or might take any other medicines.

The following medicines may enhance the effect of Dexmedetomidine
- 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 may enhance this effect. Dexmedetomidine should not be used with medicines that cause temporary paralysis.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think that you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

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

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

Dexmedetomidine contains 5.5 g glucose per 100 ml. This should be taken into account in patients with diabetes mellitus.

3. How to use Dexmedetomidine

Hospital intensive care
Dexmedetomidine is administered to you by a doctor or nurse in hospital intensive care.
Your doctor will decide on a suitable dose for you.

Procedural sedation/awake sedation
Dexmedetomidine 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 depends on your age, size, general condition of health, the level of sedation needed and how you respond to the medicine. Your doctor may change your dose if needed and will monitor your heart and blood pressure during the treatment.

Dexmedetomidine is given to you as an infusion (drip) into your veins.

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 Dexmedetomidine. Talk to your doctor about the use of these medicines and about the use of alcohol.

If you have been given more Dexmedetomidine than you should
If you are given too Dexmedetomidine, your blood pressure may go up or down, your heartbeat may slow down, you may breathe more slowly and you may feel more drowsy. 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.

Very common (*may affect more than 1 in 10 people*)
- slow heart rate
- low or high blood pressure.
- change in breathing pattern or stopping breathing

Common (*may affect up to 1 in 10 people*)
- chest pain or heart attack
- fast heart rate
- low or high blood sugar
- nausea, vomiting or dry mouth
- restlessness
- high temperature.
- symptoms after stopping the medicine

Uncommon (*may affect up to 1 in 100 people*)
- reduced heart function, cardiac arrest
- swelling of the stomach
- thirst.
- a condition where there is too much acid in the body
- low albumin level in blood
- shortness of breath
- hallucinations
- the medicine is not effective enough

Not known (*frequency cannot be estimated from the 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 effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Dexmedetomidine

Keep this medicine out of the sight and reach of children.

This medicinal product does not require any special storage conditions,

Do not use this medicine after the expiry date which is stated on the bag. The expiry date refers to the last day of that month.

Your doctor, nurse or pharmacist knows how to store Dexmedetomidine properly (see section 6).

After first opening, Dexmedetomidine should preferably be used immediately.

Do not throw away any medicines via wastewater.

6. Contents of the pack and other information

What Dexmedetomidine contains
The active substance Dexmedetomidine is dexmedetomidine. Each ml contains dexmedetomidine hydrochloride equivalent to 4 micrograms dexmedetomidine.
The other ingredients are: glucose monohydrate and water for injection.

What Dexmedetomidine looks like and contents of the pack
Dexmedetomidine is supplied as a solution in a clear, colorless bag. One bag contains 100 ml solution.

Dexmedetomidine is supplied as
- 100 ml solution in a 100 ml flexible Polypropylene bag with an aluminium overpouch

Each Polypropylene bag contains one non PVC point for filling and closure of the bag port and one non PVC administration port.

Pack sizes:
Polypropylene bag: 1 x 100 ml, 4 x 100 ml

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer Holder:
Altan Pharma Limited
The Lennox Building
50 South Richmond Street
Dublin 2
D02 FK02, Ireland

Manufacturer:
Altan Pharmaceuticals S.A.
Polígono Industrial de Bernedo, s/n
01118 Bernedo (Álava)- Spain

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder

This leaflet was last revised in April 2023
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The following information is intended for healthcare professionals only:

Dexmedetomidine 4 micrograms/ml solution for infusion

Method of administration
Dexmedetomidine should be administered by healthcare professionals skilled in the management of patients requiring intensive care or in the anaesthetic management of patients in the operating room

- Dexmedetomidine should not be diluted before use: it is supplied ready to use.

- For single use only. Any unused solution should be discarded. Only clear solution free from particles and discoloration should be used.
- Dexmedetomidine must be administered only as an intravenous infusion using a controlled infusion device.
- Dexmedetomidine should not be given as a bolus dose.

Posology

Indication 1. For sedation of adult ICU (Intensive Care Unit) patients requiring a sedation level not deeper than arousal in response to verbal stimulation (corresponding to Richmond Agitation-Sedation Scale (RASS) 0 to -3).

Patients already intubated and sedated may switch to dexmedetomidine with an initial infusion rate of 0.7 micrograms/kg/h which may then be adjusted stepwise within the dose range 0.2 to 1.4 micrograms/kg/h in order to achieve the desired level of sedation, depending on the patient's response. A lower starting infusion rate should be considered for frail patients. Dexmedetomidine is very potent and the infusion rate is given per **hour**. After dose adjustment, a new steady state sedation level may not be reached for up to one hour.

Maximum dose: The maximum dose of 1.4 micrograms/kg/h should not be exceeded. Patients failing to achieve an adequate level of sedation with the maximum dose of dexmedetomidine should be switched to an alternative sedative agent.

Indication 2. For sedation of non-intubated adult patients prior to and/or during diagnostic or surgical procedures requiring sedation, i.e. procedural/awake sedation. ´

Initiation of Procedural Sedation: A loading infusion of 1.0 microgram/kg over 10 minutes. For less invasive procedures such as ophthalmic surgery, a loading infusion of 0.5 micrograms/kg given over 10 minutes may be suitable

Maintenance of Procedural Sedation: The maintenance infusion is generally initiated at 0.6-0.7 microgram/kg/hour and titrated to achieve desired clinical effect with doses ranging from 0.2 to 1 microgram/kg/hour. The rate of the maintenance infusion should be adjusted to achieve the targeted level of sedation.-

Shelf life:
The solution for infusion should be used immediately, after first opening.