Package leaflet: Information for the user

Dexmedetomidine 100 micrograms/ml concentrate for 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. 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.

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
Dexmedetomidine should not be used during pregnancy or breast-feeding unless clearly necessary. Ask your doctor for advice before having this medicine.

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 sodium
This medicine contains less than 1 mmol sodium (23 mg) per each ml, that is to say essentially 'sodium-free'.

3. How to use Dexmedetomidine

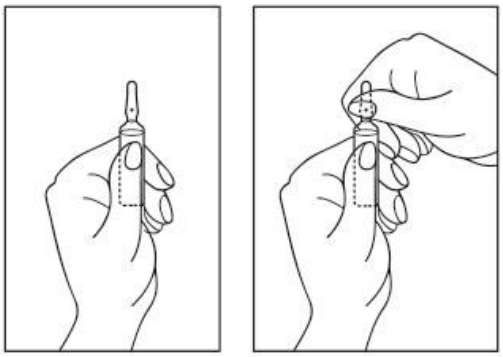
Hospital intensive care
Dexmedetomidine is administered to you by a doctor or nurse in hospital intensive care.

Procedural sedation/awake sedation
Dexmedetomidine is administered to you by a doctor or a 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 diluted and it is given to you as an infusion (drip) into your veins.

Instruction of ampoule opening:
1) Turn the ampoule with coloured point up. If there is any solution in the upper part of the ampoule, gently tap with your finger to get all the solution to the lower part of the ampoule.
2) Use both hands to open; while holding the lower part of the ampoule in one hand, use the other hand to break off the upper part of the ampoule in the direction away from the coloured point (see the pictures below).



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. 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 much 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 or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

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
- high temperature
- symptoms after stopping the medicine

Uncommon (*affects 1 to 10 users in 1,000*)
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Website: www.hpra.ie.
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 medicine does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the label and carton after {EXP}. The expiry date refers to the last day of that month.

6. Contents of the pack and other information

What Dexmedetomidine contains
- The active substance is dexmedetomidine. Each ml of concentrate contains dexmedetomidine hydrochloride equivalent to 100 micrograms dexmedetomidine.
- The other ingredients are sodium chloride and water for injections.
  Each 2 ml ampoule contains 200 micrograms of dexmedetomidine (as hydrochloride).
  Each vial (4 ml filling volume) contains 400 micrograms of dexmedetomidine (as hydrochloride).
  Each vial (10 ml filling volume) contains 1000 micrograms of dexmedetomidine (as hydrochloride).

  The concentration of the final solution after dilution should be either 4 micrograms/ml or 8 micrograms/ml.

What Dexmedetomidine looks like and contents of the pack
Concentrate for solution for infusion (sterile concentrate).
The concentrate is clear colourless or yellowish solution.

Dexmedetomidine is produced in 2 ml colourless glass ampoules and colourless glass vials (4 ml or 10 ml filling volume).

Pack sizes:
5 or 25 ampoules of 2 ml
1 or 4 vials with 4 ml
1 or 4 vials with 10 ml

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
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This medicine is authorised in the Member States of the European Economic Area under the following names:

Denmark	Dexmedetomidin Kalceks
Austria	Dexmedetomidin Kalceks 100 Mikrogramm/ml Konzentrat zur Herstellung einer Infusionslösung
Belgium	Dexmedetomidine Kalceks 100 microgrammes/ml solution à diluer pour perfusion Dexmedetomidine Kalceks 100 microgram/ml concentraat voor oplossing voor infusie Dexmedetomidine Kalceks 100 Mikrogramm/ml Konzentrat zur Herstellung einer Infusionslösung
Bulgaria	Дексмедетомидин Калцекс 100 микрограма/ml концентрат за инфузионен разтвор
Croatia	Deksmedetomidin Kalceks 100 mikrograma/ml koncentrat za otopinu za infuziju
Czech Republic	Dexmedetomidine Kalceks
Estonia	Dexmedetomidine Kalceks
Finland	Dexmedetomidine Kalceks
France	DEXMEDETOMIDINE KALCEKS 100 microgrammes/mL, solution à diluer pour perfusion
Germany	Dexmedetomidin Ethypharm 100 Mikrogramm/ml Konzentrat zur Herstellung einer Infusionslösung
Hungary	Dexmedetomidine Kalceks 100 mikrogramm/ml koncentrátum oldatos infúzióhoz
Ireland	Dexmedetomidine 100 micrograms/ml concentrate for solution for infusion
Italy	Dexmedetomidina Kalceks
Latvia	Dexmedetomidine Kalceks 100 mikrogrami/ml koncentrāts infūziju šķīduma pagatavošanai
Lithuania	Dexmedetomidine Kalceks 100 mikrogramų/ml koncentratas infuziniam tirpalui
Norway	Dexmedetomidine Kalceks
Poland	Dexmedetomidine Kalceks
Portugal	Dexmedetomidina Kalceks
Romania	Dexmedetomidină Kalceks 100 micrograme/ml concentrat pentru soluţie perfuzabilă
Slovakia	Dexmedetomidine Kalceks 100 mikrogramov/ml infúzny koncentrát
Slovenia	Deksmedetomidin Kalceks 100 mikrogramov/ml koncentrat za raztopino za infundiranje
Spain	Dexmedetomidina Kalceks 100 microgramos/ml concentrado para solución para perfusión EFG
Sweden	Dexmedetomidine Kalceks
The Netherlands	Dexmedetomidine Kalceks 100 microgram/ml concentraat voor oplossing voor infusie

This leaflet was last revised in 02/2022

The following information is intended for healthcare professionals only:

Dexmedetomidine 100 micrograms/ml concentrate for 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. It must be administered only as a diluted intravenous infusion using a controlled infusion device.

Preparation of solution
This medicine can be diluted in glucose 50 mg/ml (5%), Ringers, Lactated Ringer, mannitol or sodium chloride 9 mg/ml (0.9%) solution for injection to achieve the required concentration of either 4 micrograms/ml or 8 micrograms/ml prior to administration. Please see below in tabulated form the volumes needed to prepare the infusion.

In case the required concentration is 4 micrograms/ml:

Volume of Dexmedetomidine 100 micrograms/ml concentrate for solution for infusion	**Volume of diluent**	**Total volume of infusion**
2 ml	48 ml	50 ml
4 ml	96 ml	100 ml
10 ml	240 ml	250 ml
20 ml	480 ml	500 ml

In case the required concentration is 8 micrograms/ml:

Volume of Dexmedetomidine 100 micrograms/ml concentrate for solution for infusion	**Volume of diluent**	**Total volume of infusion**
4 ml	46 ml	50 ml
8 ml	92 ml	100 ml
20 ml	230 ml	250 ml
40 ml	460 ml	500 ml

The solution should be shaken gently to mix well.

This medicine should be inspected visually for particulate matter and discoloration prior to administration.

This medicine has been shown to be compatible when administered with the following intravenous fluids and medicinal products:

Lactated Ringers, 5% glucose solution, sodium chloride 9 mg/ml (0.9%) solution for injection, mannitol 200 mg/ml (20%), thiopental sodium, etomidate, vecuronium bromide, pancuronium bromide, succinylcholine, atracurium besylate, mivacurium chloride, rocuronium bromide, glycopyrrolate bromide, phenylephrine HCl, atropine sulfate, dopamine, noradrenaline, dobutamine, midazolam, morphine sulfate, fentanyl citrate, and a plasma-substitute.

Incompatibilities
There is a potential for adsorption of dexmedetomidine to some types of natural rubber. Although dexmedetomidine is dosed to effect, it is advisable to use components with synthetic or coated natural rubber gaskets.

Shelf life after dilution
Chemical and physical in-use stability of the diluted infusions has been demonstrated for 36 hours at 25°C and at refrigerated conditions (2°C – 8°C).

From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to the use are the responsibility of the user and would not normally be longer than 24 hours at 2° to 8°C, unless dilution has taken place in controlled and validated aseptic conditions.