

Package leaflet: Information for the patient

Dexmedetomidine 100 microgram/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
2. What you need to know before you are given Dexmedetomidine
3. How Dexmedetomidine is given
4. Possible side effects
5. How to store Dexmedetomidine
6. Contents of the pack and other information

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

Talk to your doctor or nurse before you are given this medicine 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 mortality risk has been seen for patients 65 years of age and under when using this medicine, especially for patients admitted to the intensive care unit for other reasons than after surgery with a more severe disease condition 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 take into account the benefit and risks of this medicine for you, compared to 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 (such as midazolam, propofol),
- strong pain medicines (like opioids such as morphine, codeine),
- anaesthetic medicines (such as sevoflurane, isoflurane).

If you are using medicines which lower your blood pressure and heart rate, using them together 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 you are given this medicine.

Driving and using machines

This medicine 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 3.54 mg sodium (main component of cooking/table salt) in each mL. This is equivalent to 0.18% of the recommended maximum daily dietary intake of sodium for an adult.

3. How Dexmedetomidine is given

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, such as 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.

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 are 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 (sleepy). 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 (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 (feeling sick), vomiting (being sick) 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 HPRC 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.

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

This medicine does not require any special storage conditions.

Do not use this medicine if you notice any particles or discoloration.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

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.
Each ampoule of 2 ml contains 200 micrograms of dexmedetomidine.
Each vial of 4 ml contains 400 micrograms of dexmedetomidine.
Each vial of 10 ml contains 1,000 micrograms of dexmedetomidine.
The concentration of the final solution after dilution should be either 4 microgram/ml or 8 microgram/ml.
- The other ingredients are sodium chloride and water for injections.

What Dexmedetomidine looks like and contents of the pack

Concentrate for solution for infusion (sterile concentrate).

The concentrate is a clear, colourless solution, free from visible particles.

Containers

Glass ampoules

Glass vials

Pack sizes

5 x 2 ml ampoules

10 x 4 ml vials

1 x 10 ml vials, 10 x 10 ml vials

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorization Holder

Noridem Enterprises Limited

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Manufacturer

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This medicine is authorised in the Member States of the European Economic Area under the following names:

Sweden	Dexmedetomidine Noridem
Austria	Dexmedetomidin Noridem 100 Mikrogramm/ml Konzentrat zur Herstellung einer Infusionslösung

Cyprus	Dexmedetomidine Noridem 100 μικρογραμμάρια/ml πυκνό διάλυμα για παρασκευή διαλύματος προς έγχυση
Czech Republic	Dexmedetomidine Noridem
Germany	Dexmedetomidin Noridem 100 Mikrogramm/ml Konzentrat zur Herstellung einer Infusionslösung
Denmark	Dexmedetomidine Noridem
Greece	Dexmedetomidine/Demo
Spain	Dexmedetomidina Noridem 100 microgramos/ml concentrado para solución para perfusión EFG
Finland	Dexmedetomidine Noridem
Hungary	Dexmedetomidin Noridem 100 mikrogramm/ml koncentrátum oldatos injekcióhoz
Ireland	Dexmedetomidine 100 microgram/ml concentrate for solution for infusion
Italy	Dexmedetomidina Noridem
The Netherlands	Dexmedetomidine Noridem 100 microgram/ml, concentraat voor oplossing voor infusie
Norway	Dexmedetomidine Noridem
Poland	Dexmedetomidinum Noridem
Slovakia	Dexmedetomidine Noridem

This leaflet was last revised in

The following information is intended for healthcare professionals only:

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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

Dexmedetomidine can be diluted in glucose 50 mg/ml (5%), Lactated Ringers, mannitol 200 mg/ml (20%) 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 microgram/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 microgram/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.

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

Dexmedetomidine 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.

Compatibility studies have shown 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 of the diluted solution

Chemical and physical in-use stability has been demonstrated for 24 hours at 25°C under artificial light or at 2° - 8°C when diluted with sodium chloride 9 mg/ml (0.9%), glucose 50 mg/ml (5%), Lactated Ringers and mannitol 200 mg/ml (20%).

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.