Package leaflet: Information for the user

Dexmedetomidine 100 micrograms/ml concentrate for solution for infusion
dexmedetomidine

The name of your medicine is Dexmedetomidine 100 micrograms/ml concentrate for solution for infusion which will be referred to as Dexmedetomidine throughout this leaflet.

Read all of this leaflet carefully before you start using 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

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.

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.

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.

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)
- increased need to pass urine

Reporting of side effects
If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Ireland
HPRA Pharmacovigilance
Website: www.hpra.ie

United Kingdom
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

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 label and carton after EXP.

This medicine does not require any special temperature storage conditions.

After dilution

Chemical and physical in-use stability has been demonstrated for 24 hours at 25°C.

From a microbiological point of view, unless the method of dilution precludes the risk of microbiological contamination, 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.

Do not refrigerate.

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 2 ml vial contains 200 micrograms of dexmedetomidine (as hydrochloride).

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

Container
2 ml glass vials

Pack size
5 x 2 ml vials

Marketing Authorisation Holder
Ireland
Baxter Holding B.V.
Kobaltweg 49,
3542CE Utrecht,
Netherlands

United Kingdom
Baxter Healthcare Limited,
Caxton Way,
Thetford,
Norfolk,
IP24 3SE,
United Kingdom

Manufacturer
UAB Norameda
Meistru 8a,
Vilnius, 02189, Lithuania

Bieffe Medital S.p.A
Via Nuova Provinciale
23034 Grosotto (SO)
Italy

This medicinal product is authorised in the Member States of the EEA under the following names:

Netherlands	Dexmedetomidine Baxter 100 microgram/ml concentraat voor oplossing voor infusie
Austria	Dexmedetomidin Baxter 100 Mikrogramm/ml Konzentrat zur Herstellung einer Infusionslösung
Belgium	Dexmedetomidine Baxter 100 microgrammes/ml solution à diluer pour perfusion
Denmark	Dexmedetomidine Baxter
Finland	Dexmedetomidine Baxter 100 mikrog/ml infuusiokonsentraatti, liuosta varten
France	DEXMEDETOMIDINE BAXTER 100 microgrammes/mL, solution à diluer pour perfusion
Germany	Dexmedetomidin Baxter 100 Mikrogramm/ml Konzentrat zur Herstellung einer Infusionslösung
Greece	Dexmedetomidine/Baxter 100 μg/ml πυκνό διάλυμα για παρασκευή διαλύματος προς έγχυση
Ireland	Dexmedetomidine 100 micrograms/ml concentrate for solution for infusion
Italy	Dexmedetomidina Baxter
Norway	Dexmedetomidine Baxter
Portugal	Dexmedetomidina Baxter
Spain	Dexmedetomidina Baxter 100 microgramos/ml Concentrado para solución para perfusión EFG
Sweden	Dexmedetomidine Baxter
Cyprus	Dexmedetomidine/Baxter 100 μg/ml πυκνό διάλυμα για παρασκευή διαλύματος προς έγχυση
Luxembourg	Dexmedetomidine Baxter 100 microgrammes/ml, solution à diluer pour perfusion
United Kingdom	Dexmedetomidine 100 micrograms/ml concentrate for solution for infusion

This leaflet was last revised in 05/2021

----------**TEAR-OFF SECTION BELOW** ----------

The following information is intended for healthcare professionals only:

Dexmedetomidine 100 micrograms/ml concentrate for solution for infusion

Method of administration

Dexmedetomidine 100 micrograms/ml concentrate for solution for infusion 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 100 micrograms/ml concentrate for solution for infusion 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	Volume of diluent	Total volume of infusion

micrograms/ml concentrate for solution for 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.

Dexmedetomidine 100 micrograms/ml concentrate for solution for infusion should be inspected visually for particulate matter and discoloration prior to administration.

Dexmedetomidine 100 micrograms/ml concentrate for solution for infusion 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

Chemical and physical in-use stability has been demonstrated for 24 hours at 25°C.

From a microbiological point of view, unless the method of dilution precludes the risk of microbiological contamination, 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.

Do not refrigerate.