Package leaflet: Information for the user

Dexmedetomidine B. Braun 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 B. Braun is and what it is used for

Dexmedetomidine B. Braun 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 B. Braun

You must not be given Dexmedetomidine B. Braun
- 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 B. Braun 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 B. Braun
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 B. Braun:

- 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 B. Braun may enhance this effect. Dexmedetomidine B. Braun should not be used with medicines that cause temporary paralysis.

Pregnancy and breast-feeding
Dexmedetomidine B. Braun 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 B. Braun has major impact on the ability to drive and use machines. After you have been given Dexmedetomidine B. Braun 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 B. Braun contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per each ampoule of 2 ml and 4 ml, that is to say essentially ‘sodium-free’.

This medicine contains 35.4 mg sodium (main component of cooking/table salt) in each ampoule of 10 ml. This is equivalent to 1.8% of the recommended maximum daily dietary intake of sodium for an adult.

3. How to use Dexmedetomidine B. Braun

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

Procedural sedation/awake sedation
Dexmedetomidine B. Braun 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 B. Braun 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 B. Braun 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 B. Braun. Talk to your doctor about the use of these medicines and about the use of alcohol.

If you have been given more Dexmedetomidine B. Braun than you should
If you are given too much Dexmedetomidine B. Braun, 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 abdomen
- 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, nurse 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 B. Braun

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 ampoule label after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

After dilution
Do not refrigerate.
Chemical and physical in-use stability has been demonstrated for 48 hours at 25 °C.
From a microbiological point of view, unless the method of opening precludes the risk of microbial contamination, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user.

Do not use this medicine if you notice that the solution is not clear, colourless and free from particulate matter.

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 B. Braun contains
- The active substance is dexmedetomidine. Each ml of concentrate contains dexmedetomidine hydrochloride equivalent to 100 micrograms dexmedetomidine.

Each ampoule of 2 ml contains dexmedetomidine hydrochloride equivalent to 200 micrograms of dexmedetomidine.
Each ampoule of 4 ml contains dexmedetomidine hydrochloride equivalent to 400 micrograms of dexmedetomidine.
Each ampoule of 10 ml contains dexmedetomidine hydrochloride equivalent to 1000 micrograms of dexmedetomidine.

- 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 B. Braun looks like and contents of the pack
Concentrate for solution for infusion (sterile concentrate).

The concentrate is a clear, colourless solution.

Containers
2, 4 or 10 ml colourless glass ampoules

Pack sizes
5 x 2 ml, 10 x 2 ml, 25 x 2 ml ampoules
4 x 4 ml, 10 x 4 ml ampoules
4 x 10 ml, 10 x 10 ml ampoules

Not all pack sizes may be marketed.

Marketing Authorisation Holder:
B. Braun Melsungen AG
Carl-Braun-Straße 1
34212 Melsungen
Germany

Manufacturer:

B. Braun Medical, S.A.
Ronda de los Olivares, Parcela 11, Polígono Industrial Los Olivares
23009 Jaén
Spain

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

Austria	Dexmedetomidin B. Braun 100 Mikrogramm/ml Konzentrat zur Herstellung einer Infusionslösung
Belgium	Dexmedetomidine B. Braun 100 microgram/ ml.
Czech Republic	Dexmedetomidine B. Braun
Denmark	Dexmedetomidine B. Braun
Finland	Dexmedetomidine B. Braun 100 µg/ ml infuusiokonsentraatti, liuosta varten
Germany	Dexmedetomidin B. Braun 100 Mikrogramm/ml Konzentrat zur Herstellung einer Infusionslösung
Hungary	Dexmedetomidine B. Braun 100 µg/ ml koncentrátum oldatos infúzióhoz
Ireland	Dexmedetomidine B. Braun 100 micrograms/ml concentrate for solution for infusion
Italy	Dexmedetomidina B. Braun
Lithuania	Dexmedetomidine B. Braun 100 mikrogramų/ ml koncentratas infuziniam tirpalui
Netherlands	Dexmedetomidine B. Braun 100 µg/ ml oplossing voor infusie
Norway	Dexmedetomidine B. Braun
Portugal	Dexmedetomidina B. Braun 100 µg/ ml concentrado para solução para perfusão
Slovak Republic	Dexmedetomidine B. Braun 100 µg/ ml infúzny koncentrát
Slovenia	Deksmedetomidin B. Braun 100 mikrogramov/ ml koncentrat za raztopino za infundiranje
Spain	Dexmedetomidina B. Braun 100 microgramos/ mL concentrado para solución para perfusión
Sweden	Dexmedetomidine B. Braun 100 µg/ ml koncentrat till infusionsvätska, lösning

This leaflet was last revised in August 2024.

The following information is intended for healthcare professionals only:

Dexmedetomidine B. Braun concentrate for solution for infusion

Method of administration
Dexmedetomidine B. Braun 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 B. Braun can be diluted in glucose 50 mg/ml (5%), Ringers, 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 the case the required concentration is 4 micrograms/ml:

Volume of Dexmedetomidine B. Braun 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 the case the required concentration is 8 micrograms/ml:

Volume of Dexmedetomidine B. Braun 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.

Before administration, the solution should be visually inspected to ensure it is clear and colourless. It should not be used if any particulate matter is observed.

Dexmedetomidine B. Braun 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, 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 after dilution
Do not refrigerate.
Chemical and physical in-use stability has been demonstrated for 48 hours at 25 °C.
From a microbiological point of view, unless the method of opening precludes the risk of microbial contamination, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user.