PACKAGE LEAFLET

Package leaflet: Information for the user

Dexmedetomidine Kabi 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 Kabi is and what it is used for

Dexmedetomidine Kabi 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 Kabi

You must not be given Dexmedetomidine Kabi
- 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 are given this medicine, tell your doctor or nurse if any of the following apply as Dexmedetomidine Kabi 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 Kabi
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 Kabi:
- 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 Kabi may enhance this effect. Dexmedetomidine Kabi should not be used with medicines that cause temporary paralysis.

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

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

Driving and using machines
Dexmedetomidine Kabi has major impact on the ability to drive and use machines. After you have been given Dexmedetomidine Kabi 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 Kabi contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially “sodium free”.

3. How to use Dexmedetomidine Kabi

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

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

If you have been given more Dexmedetomidine Kabi than you should
If you are given too much Dexmedetomidine Kabi, 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*)
- 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 nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

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

For IE: 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 Kabi

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'. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not use if the vial is damaged or broken.

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 Kabi 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 vial contains 200 micrograms of dexmedetomidine.
Each 4 ml vial contains 400 micrograms of dexmedetomidine.
Each 10 ml vial contains 1000 micrograms of dexmedetomidine.
The concentration of the final solution after dilution should be either 4 micrograms/ml or 8 micrograms/ml.

What Dexmedetomidine Kabi looks like and contents of the pack

Concentrate for solution for infusion (sterile concentrate).
The concentrate is a clear, colourless solution.

Containers
2 ml, 4 ml or 10 ml glass vials.

Pack sizes
10 x 2 ml vials
25 x 2 ml vials
1 x 4 ml vial
4 x 4 ml vials
10 x 4 ml vials
4 x 10 ml vials
10 x 10 ml vials

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Fresenius Kabi Deutschland GmbH
Else-Kroener Strasse 1,
Bad Homburg v.d.H. 61352,
Germany

Manufacturer
Fresenius Kabi Austria GmbH
Hafnerstrasse 36
8055 Graz
Austria

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Name of the Member State	Name of the medicinal product
Austria	Dexmedetomidin Kabi 100 Mikrogramm/ml Konzentrat zur Herstellung einer Infusionslösung
Belgium	Dexmedetomidine Kabi 100 mcg/ml, Concentraat voor oplossing voor infusie Solution à diluer pour perfusion Konzentrat zur Herstellung einer Infusionslösung
Bulgaria	Дексмедетомидин Каби 100 микрограма/ml концентрат за инфузионен разтвор
Croatia	Deksmedetomidin Kabi 100 mikrograma/ml koncentrat za otopinu za infuziju
Cyprus	Dexmedetomidine/Kabi 100 μg/mL πυκνό διάλυμα για παρασκευή διαλύματος προς έγχυση
Czech Republic	Dexmedetomidine Kabi
Denmark	Dexmedetomidine Kabi
Estonia	Dexmedetomidine Kabi
Finland	Dexmedetomidine Kabi 100 µg/ml infuusiokonsentraatti, liuosta varten
France	DEXMEDETOMIDINE KABI 100 microgrammes/mL, solution à diluer pour perfusion
Germany	Dexmedetomidin Kabi 100 Mikrogramm/ml Konzentrat zur Herstellung einer Infusionslösung
Greece	Dexmedetomidine/Kabi 100 μg/mL πυκνό διάλυμα για παρασκευή διαλύματος προς έγχυση
Hungary	Dexmedetomidine Kabi 100 mikrogramm/ml koncentrátum oldatos infúzióhoz
Ireland	Dexmedetomidine Kabi 100 micrograms/ml concentrate for solution for infusion
Italy	Dexmedetomidina Kabi
Lithuania	Dexmedetomidine Kabi 100 mikrogramų/ml koncentratas infuziniam tirpalui
Luxembourg	Dexmedetomidin Kabi 100 µg/ml Konzentrat zur Herstellung einer Infusionslösung
Malta	Dexmedetomidine Kabi 100 µg/mL
Netherlands	Dexmedetomidine Kabi 100 mcg/ml, concentraat voor oplossing voor infusie
Norway	Dexmedetomidine Kabi
Poland	Dexmedetomidine Kabi
Portugal	Dexmedetomidina Kabi
Romania	Dexmedetomidină Kabi 100 microgramе/ml concentrat pentru soluție perfuzabilă
Slovakia	Dexmedetomidine Kabi 100 µg/mL
Slovenia	Deksmedetomidin Kabi 100 mikrogramov/ml koncentrat za raztopino za infundiranje
Spain	Dexmedetomidina Kabi 100 µg/mL concentrado para solución para perfusión EFG
Sweden	Dexmedetomidine Kabi
United Kingdom (Northern Ireland)	Dexmedetomidine Kabi 100 micrograms/ml concentrate for solution for infusion

This leaflet was last revised in August 2022.

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The following information is intended for healthcare professionals only:

Dexmedetomidine Kabi 100 micrograms/mL concentrate for solution for infusion

Method of administration
Dexmedetomidine Kabi 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 Kabi can be diluted in the following infusion fluids to achieve the required concentration of either 4 micrograms/ml or 8 micrograms/ml prior to administration:

- Sodium chloride 9 mg/mL (0.9%)
- Glucose 50 mg/mL (5%)
- Ringer's solution
- Lactated Ringers
- Mannitol 200 mg/mL (20%)

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 Kabi 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 Kabi 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 Kabi 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.

Shelf life
Chemical and physical in-use stability has been demonstrated for 24 hours at 25 °C and for 24 hours at 2 ° C to 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 use are the responsibility of the user and would normally not be longer than 24 hours at 2° to 8° C, unless dilution has taken place in controlled and validated aseptic conditions.