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Dexmedetomidine Accord (*dexmedetomidine*)

An overview of Dexmedetomidine Accord and why it is authorised in the EU

What is Dexmedetomidine Accord and what is it used for?

Dexmedetomidine Accord is a medicine used to sedate (calm or make sleepy) adults in the following settings:

- in hospital intensive care units to bring about a light level of sedation in which the patient can still respond to verbal stimulation (corresponding to a score of between 0 and -3 on the Richmond Agitation-Sedation Scale);
- before or during diagnostic or surgical procedures where the patient remains awake (awake sedation).

Dexmedetomidine Accord contains the active substance dexmedetomidine.

Dexmedetomidine Accord is a 'generic medicine'. This means that Dexmedetomidine Accord contains the same active substance and works in the same way as a 'reference medicine' already authorised in the EU called Dexdor. For more information on generic medicines, see the question-and-answer document here.

How is Dexmedetomidine Accord used?

Dexmedetomidine Accord can only be obtained with a prescription and should be given by a healthcare professional skilled in managing patients in intensive care or giving anaesthetic during diagnostic or surgical procedures.

Dexmedetomidine Accord is given by infusion (drip) into a vein using a controlled infusion device.

When Dexmedetomidine Accord is used in intensive care, the dose is adjusted to achieve the desired level of sedation. If sedation with the maximum dose is not adequate, the patient should be switched to other medicines.

When Dexmedetomidine Accord is used for awake sedation in diagnostic or surgical procedures, the starting dose depends on the type of procedure and the dose is adjusted to achieve the desired effect. In some cases, the patient is also given a local anaesthetic, painkillers and other sedative medicines. The patient's blood pressure, heart rate, breathing and oxygen levels should be monitored closely during the procedure.

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Care should be taken when using Dexmedetomidine Accord in patients with reduced liver function and the dose may be reduced.

For more information about using Dexmedetomidine Accord, see the package leaflet or contact your doctor or pharmacist.

How does Dexmedetomidine Accord work?

The active substance in Dexmedetomidine Accord, dexmedetomidine, is a selective alpha-2 receptor agonist. It works by acting on receptors (targets) in the brain called alpha-2 receptors and reducing the activity of the sympathetic nervous system which is involved in controlling anxiety, arousal and sleep as well as blood pressure and heart rate. By reducing the activity of the sympathetic nervous system, dexmedetomidine helps to make patients calm or sleepy.

How has Dexmedetomidine Accord been studied?

Studies on the benefits and risks of the active substance in the authorised uses have already been carried out with the reference medicine, Dexdor, and do not need to be repeated for Dexmedetomidine Accord.

As for every medicine, the company provided studies on the quality of Dexmedetomidine Accord. There was no need for 'bioequivalence' studies to investigate whether Dexmedetomidine Accord is absorbed similarly to the reference medicine to produce the same level of the active substance in the blood. This is because Dexmedetomidine Accord is given by infusion into a vein, so the active substance is delivered straight into the bloodstream.

What are the benefits and risks of Dexmedetomidine Accord?

Because Dexmedetomidine Accord is a generic medicine, its benefits and risks are taken as being the same as the reference medicine's.

Why is Dexmedetomidine Accord authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Dexmedetomidine Accord has been shown to be comparable to Dexdor. Therefore, the Agency's view was that, as for Dexdor, the benefits of Dexmedetomidine Accord outweigh the identified risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Dexmedetomidine Accord?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Dexmedetomidine Accord have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Dexmedetomidine Accord are continuously monitored. Side effects reported with Dexmedetomidine Accord are carefully evaluated and any necessary action taken to protect patients.

Other information about Dexmedetomidine Accord

Dexmedetomidine Accord received a marketing authorisation valid throughout the EU on 13 February 2020.

Further information on Dexmedetomidine Accord can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/dexmedetomidine-accord. Information on the reference medicine can also be found on the Agency's website.

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