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Dexdor (*dexmedetomidine*)

An overview of Dexdor and why it is authorised in the EU

What is Dexdor and what is it used for?

Dexdor is a medicine used to sedate (calm or make sleepy) adult patients 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).

Dexdor contains the active substance dexmedetomidine.

How is Dexdor used?

Dexdor 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.

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

When Dexdor 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 can be switched to other medicines.

When Dexdor 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.

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

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

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How does Dexdor work?

The active substance in Dexdor, dexmedetomidine, is a selective alpha-2 receptor agonist. It works by blocking receptors in the brain called alpha-2 receptors and reduces 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.

What benefits of Dexdor have been shown in studies?

Sedation in intensive care

Dexdor was compared with other sedative medicines (propofol or midazolam) in two main studies involving 1,000 patients who required sedation in intensive care units. The main measures of effectiveness were how well the medicines maintained the required sedation level and the time patients needed to spend on a mechanical ventilator (a machine that 'breathes' for the patient).

In the first study, 65% of patients given Dexdor maintained the required level of sedation compared with 65% of those receiving propofol. In the second study, 61% of patients given Dexdor maintained the required level of sedation compared with 57% of those receiving midazolam. The studies also showed that Dexdor reduced the duration of mechanical ventilation.

Awake sedation during diagnostic or surgical procedures

Dexdor was compared with placebo (a dummy treatment) in two main studies involving 431 patients. A higher proportion of patients treated with Dexdor did not require additional treatment with midazolam (another sedative medicine) to maintain the desired sedation level.

The first study involved patients undergoing surgery or a procedure under an anaesthetic block (where sensation to a part of the body is blocked). Patients in the Dexdor group received either 0.5 or 1 microgram/kg bodyweight. Midazolam treatment was not required in 40% of patients receiving the lower dose of Dexdor and 54% of those receiving the higher dose compared with 3% of patients receiving placebo.

The second study involved patients undergoing a fibreoptic intubation (inserting a breathing tube through the nose or the mouth into the windpipe) while patients are awake. Midazolam treatment was not required in 53% of patients receiving Dexdor compared with 14% receiving placebo.

What are the risks associated with Dexdor?

The most common side effects with Dexdor (which may affect more than 1 in 10 people) when it is used in intensive care are low or high blood pressure and bradycardia (slow heart rate). The most common side effects when it is used for awake sedation are low blood pressure, respiratory depression (reduced ability to breathe) and bradycardia.

Dexdor must not be used in patients with advanced heart block (a type of heart rhythm disorder), patients with uncontrolled low blood pressure and in patients with conditions such as stroke that affect the blood supply to the brain.

For the full list of side effects and restrictions with Dexdor, see the package leaflet.

Why is Dexdor authorised in the EU?

The studies in intensive care showed that Dexdor compared well with other sedatives. It is effective for awake sedation during procedures but sometimes an additional sedative medicine as well as Dexdor may be needed. Dexdor is an additional alternative medicine for achieving lighter levels of sedation in suitable patients. As dexmedetomidine has been in use in several countries as a sedative agent, its risks are well known and are considered to be manageable. The European Medicines Agency therefore decided that Dexdor's benefits are greater than its risks and it can be authorised for use in the EU.

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

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

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

Other information about Dexdor

Dexdor received a marketing authorisation valid throughout the EU on 16 September 2011.

Further information on Dexdor can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports.

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