EMA/648646/2011
EMEA/H/C/002268

**EPAR summary for the public**

# Dexdor

dexmedetomidine

This is a summary of the European public assessment report (EPAR) for Dexdor. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Dexdor.

## What is Dexdor?

Dexdor is a medicine that contains the active substance dexmedetomidine. It is available as a concentrate to be made up into a solution for infusion (drip into a vein).

## What is Dexdor used for?

Dexdor is used to sedate (calm or make sleepy) adult patients in hospital intensive care units. Dexdor is used to bring about a relatively 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).

The medicine can only be obtained with a prescription.

## How is Dexdor used?

Dexdor is for hospital use only and should be given by a healthcare professional skilled in managing patients requiring intensive care.

Dexdor is given by infusion into a vein using a controlled infusion device. The doses are adjusted until the required level of sedation is attained. If adequate sedation is not achieved with the maximum dose, the patient should be switched to alternative sedative agent.

For more information on the use of Dexdor, including doses and dose adjustments, see the summary of product characteristics (also part of the EPAR).

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
**Telephone** +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
**E-mail** info@ema.europa.eu **Website** www.ema.europa.eu

## How does Dexdor work?

The active substance in Dexdor, dexmedetomidine, is a selective alpha-2 receptor agonist. It works by attaching to receptors in the brain called alpha-2 receptors and causes a reduction in the activity of the sympathetic nervous system which is involved in controlling people's anxiety, arousal and sleep as well the blood pressure and heart rate. By reducing the activity of the sympathetic nervous system, dexmedetomidine helps to make patients calm or sleepy.

## How has Dexdor been studied?

The effects of Dexdor were first tested in experimental models before being studied in humans.

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

## What benefit has Dexdor shown during the studies?

Dexdor compared well with the comparator medicines in maintaining sedation. In one main 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 a benefit of Dexdor in reducing the duration of mechanical ventilation.

## What is the risk associated with Dexdor?

The most frequently reported side effects with Dexdor are hypotension (low blood pressure), hypertension (high blood pressure) and bradycardia (slow heart rate), occurring in approximately 25%, 15% and 13% of patients respectively. For the full list of all side effects reported with Dexdor, see the package leaflet.

Dexdor must not be used in people who are hypersensitive (allergic) to dexmedetomidine or any of the other ingredients. It must also not be used in patients with advanced heart block (a type of heart rhythm disorder), patients with uncontrolled hypotension and in patients with conditions such as stroke that affect the blood supply to the brain.

## Why has Dexdor been approved?

The CHMP noted that the studies showed that Dexdor compared well with other sedatives and will serve as 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 Committee therefore concluded that the benefits of Dexdor are greater than its risks and recommended that it be granted marketing authorisation.

## Other information about Dexdor

The European Commission granted a marketing authorisation valid throughout the European Union for Dexdor on 16 September 2011.

The full EPAR for Dexdor can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports. For more information about treatment with Dexdor, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 08-2011.