12 December 2019
EMA/CHMP/655997/2019
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Dexmedetomidine Accord

dexmedetomidine

On 12 December 2019, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Dexmedetomidine Accord, intended for the induction of light to moderate sedation of adults in intensive care unit. The applicant for this medicinal product is Accord Healthcare S.L.U.

Dexmedetomidine Accord will be available as a concentrate for solution for infusion (100 µg/ml). The active substance of Dexmedetomidine Accord is dexmedetomidine, a sedative agent (ATC code: N05CM18) acting as a selective alpha-2 receptor agonist with a broad range of pharmacological properties. The sedative effects are mediated through decreased firing of locus coeruleus, the predominant noradrenergic nucleus situated in the brainstem. Dexmedetomidine has shown some analgesic and anaesthetic/analgesic-sparing effects.

Dexmedetomidine Accord is a generic of Dexdor, which has been authorised in the EU. Since Dexmedetomidine Accord is administered intravenously and is 100% bioavailable, a bioequivalence study versus the reference product Dexdor was not required. A question and answer document on generic medicines can be found here.

The full indication is:

> "For sedation of adult ICU (Intensive Care Unit) patients requiring a sedation level not deeper than arousal in response to verbal stimulation (corresponding to Richmond Agitation-Sedation Scale (RASS) 0 to -3).
>
> For sedation of non-intubated adult patients prior to and/or during diagnostic or surgical procedures requiring sedation, i.e. procedural/awake sedation."

It is proposed that Dexmedetomidine Accord is for hospital use only. Dexmedetomidine Accord should be administered by healthcare professionals skilled in the management of patients requiring intensive care.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.