21 July 2011
EMA/CHMP/549755/2011
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (initial authorisation)

Dexdor

dexmedetomidine

On 21 July 2011 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Dexdor, 100 micrograms/ml, concentrate for solution for infusion intended for sedation of adult Intensive Care Unit (ICU) patients. The applicant for this medicinal product is Orion Corporation. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Dexdor is dexmedetomidine hydrochloride, 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 claimed to be 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.

The benefit with Dexdor is its ability to maintain sedation level not deeper than arousal in response to verbal stimulation in adult patients already intubated and sedated. The most common side effects are related to cardiovascular disorders: bradycardia, hypotension, hypertension.

A pharmacovigilance plan for Dexdor will be implemented as part of the marketing authorisation

The approved indication is: for sedation of adult ICU patients requiring a sedation level not deeper than arousal in response to verbal stimulation (corresponding to Richmond Agitation-Sedation Scale (RASS) 0 to -3).

It is proposed that Dexdor is for hospital use only. Dexdor 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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will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit to risk balance for Dexdor and therefore recommends the granting of the marketing authorisation.