15 June 2012
EMA/CVMP/345725/2012
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1]

Dexdomitor - Extension

Dexmedetomidine

On 14 June 2012, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion,[2] recommending the extension of the marketing authorisation for the veterinary medicinal product Dexdomitor, 0.5 mg/ml, Solution for injection, intended for

Non-invasive, mildly to moderately painful, procedures and examinations which require restraint, sedation and analgesia in dogs and cats.

Deep sedation and analgesia in dogs in concomitant use with butorphanol for medical and minor surgical procedures.

Premedication in dogs and cats before induction and maintenance of general anaesthesia.

The extension dealt with the addition of a new strength containing 0.1 mg/ml dexmedetomidine hydrochloride.

The applicant for this veterinary medicinal product is Orion Corporation.

The active substance of Dexdomitor is dexmedetomidine hydrochloride, QN05CM18, a potent and selective α2-adrenoceptor agonist that inhibits the release of noradrenaline from noradrenergic neurons. Sympathetic neurotransmission is prevented and the level of consciousness decreases. Dexdomitor produces sedation and analgesia in dogs and cats. The duration and depth of the sedation and analgesia are dose-dependent. At maximal effect, the animal is relaxed, recumbent and does not respond to external stimulus.

The most common side effects are a decrease in heart rate and body temperature. In some dogs and cats, a decrease in respiratory rate may occur. Rare instances of pulmonary oedema have been reported. Blood pressure will increase initially and then return to normal or below normal. Due to peripheral vasoconstriction and venous desaturation in the presence of normal arterial oxygenation,

[1] Summaries of opinion are published without prejudice to the Commission Decision, which will normally be issued within 90 days from adoption of the opinion.
[2] Applicants may appeal any CVMP opinion, provided they notify the European Medicines Agency in writing of their intention to appeal within 15 days of receipt of the opinion.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8447
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

the mucous membranes may appear pale and/or with a blue tinge. Vomiting may occur 5-10 minutes after injection. Some dogs and cats may also vomit at the time of recovery.

Detailed conditions for the use of this product will be described in the summary of product characteristics (SPC) which will be published in the European public assessment report (EPAR) and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CVMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit to risk balance for Dexdomitor 0.1 mg/ml and therefore recommends the granting of the marketing authorisation.