The European Agency for the Evaluation of Medicinal Products
Veterinary Medicines

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COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS
EUROPEAN PUBLIC ASSESSMENT REPORT (EPAR)

DEXDOMITOR

International Nonproprietary Name (INN): **Dexmedetomidine**

Abstract

On 30 August 2002, the European Commission issued a Marketing Authorisation valid throughout the European Union for the veterinary medicinal product Dexdomitor, which contains dexmedetomidine. This decision was based on the assessment report and favourable opinion adopted by the Committee for Veterinary Medicinal Products (CVMP) on 15 May 2002. The Marketing Authorisation Holder responsible for this medicinal product is Orion Corporation of Finland.

The approved indications are for

- non-invasive, mildly to moderately painful, procedures and examinations which require restraint, sedation and analgesia in cats and dogs
- premedication in cats before induction and maintenance of general anaesthesia with an injectable dissociative agent (ketamine)
- deep sedation and analgesia in dogs in concomitant use with butorphanol for medical and minor surgical procedures

The active substance of Dexdomitor, dexmedetomine, 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.

Dexmedetomidine is 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. Reduced heart rate and temporary AV-block can be seen after administration of dexmedetomidine. Blood pressure decreases to normal or below normal levels after an initial increase. Respiration rate can occasionally decrease. Dexmedetomidine also induces a number of other α2-adrenoceptor mediated effects, which include piloerection, depression of motor and secretory functions of the gastrointestinal tract, diuresis and hyperglycaemia.

Clinical trials investigated cats and dogs in numerous veterinary centres in Germany and the United Kingdom. The racemate medetomidine has been on the market worldwide for a number of years and the efficacy of the approved doses are supported by a number of studies. The efficacy of dexmedetomidine was sufficiently supported by the submitted documentation in which dexmedetomidine was compared to the racemate in the target species. In these studies, the dextro-enantioner was as effective as the racemate, medetomidine. Minor differences in onset of effects were observed, but are of less importance, as there were no significant differences at 15-30 min after administration. The most frequent adverse events observed during treatment were vomiting 5-10 minutes after injection. Some cats may also vomit after recovery.

The CVMP, on the basis of quality, safety and efficacy data submitted, considered that the benefit to risk ratio for Dexdomitor is favourable in the approved indications.

For detailed conditions for the use of this product, scientific information or procedural aspects please refer to the relevant modules of this EPAR.

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 84 47
E-mail: mail@emea.eu.int http://www.emea.eu.int