17 June 2016
EMA/CVMP/331750/2016
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

Sedadex

International non-proprietary name (INN): dexmedetomidine

On 16 June 2016, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion[2], recommending the granting of a marketing authorisation for the veterinary medicinal product Sedadex, 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 applicant for this veterinary medicinal product is Le Vet Beheer B.V. The applicant is registered as an SME pursuant to the definition set out in Commission Recommendation 2003/361/EC.

Sedadex is a medicinal product containing dexmedetomidine hydrochloride (ATCvet code QN05CM18) as active substance, which is an α2-adrenoceptor agonist that inhibits the release of noradrenaline from noradrenergic neurons preventing sympathetic neurotransmission.

The benefits of Sedadex are its ability to produce sedation and analgesia in dogs and cats. The most common side effects are a decrease in heart rate and body temperature.

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-risk balance for Sedadex and therefore recommends the granting of the marketing authorisation.

[1] Summaries of opinion are published without prejudice to the Commission Decision, which will normally be issued 67 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.

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