13 April 2015
EMA/CVMP/123810/2015
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

Sileo

International non-proprietary name (INN): dexmedetomidine hydrochloride

On 10 April 2015, 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 Sileo 0.1 mg/ml oromucosal gel, intended for the alleviation of acute anxiety and fear associated with noise in dogs. The applicant for this veterinary medicinal product is Orion Corporation.

The active substance of Sileo is dexmedetomidine hydrochloride, a sedative substance, which is a selective alpha-2 adrenergic receptor agonist (alpha-2 agonist) that works by reducing the activity of the sympathetic nervous system and so helps to make the dog calm or sleepy.

The benefits of Sileo are its efficacy in the alleviation of acute anxiety and fear associated with noise in dogs. The most common side effects are transient paleness of mucous membranes at the application site, sedation, emesis and urinary incontinence.

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 Sileo 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 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.

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