16 February 2018
EMA/CVMP/679647/2017
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

Clevor

International non-proprietary name (INN): ropinirole

On 15 February 2018, 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 Clevor 30 mg/ml eye drops, solution in single-dose container, intended for the induction of vomiting in dogs. The applicant for this veterinary medicinal product is Orion Corporation.

Clevor is an emetic medicinal product containing ropinirole (as the hydrochloride) (ATCvet code QN04BC04) as the active substance. Ropinirole is a dopamine agonist which induces vomiting by activating receptors in the chemoreceptor trigger zone in the brain.

The benefits of Clevor are its efficacy in the induction of vomiting. The product also provides a new route of administration for an emetic medicine for dogs, and would increase the range of available treatment options. The most common side effects are transient mild or moderate hyperaemia of the eye, ocular discharge, protrusion of the third eyelid and blepharospasm, transient mild lethargy and increased heart rate.

The appropriate CVMP guidelines on data requirements for veterinary medicinal products intended for minor use or minor species/limited markets have been applied in the assessment of the application.

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 Clevor 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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