EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

18 April 2017
EMA/CVMP/192928/2017
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

Prevomax

International non-proprietary name (INN): maropitant

On 12 April 2017, 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 Prevomax, a solution for subcutaneous or intravenous injection intended for the treatment and prevention of emesis and/or nausea in dogs and cats. 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.

Prevomax is an anti-emetic medicinal product containing maropitant (ATCvet code QA04AD90) as active substance, a neurokinin antagonist which acts in the central nervous system (CNS) by inhibiting substance P, the key neurotransmitter involved in vomiting.

The benefits of Prevomax are its efficacy in use in dogs and cats for prevention of vomiting (except that induced by motion sickness), and for the treatment of vomiting in combination with other supportive measures. Prevomax is also indicated in cats for the reduction of nausea (except that induced by motion sickness), and in dogs for the treatment and prevention of nausea induced by chemotherapy, and for the prevention of perioperative nausea and vomiting and improvement in recovery from general anaesthesia, after use of the μ-opiate receptor agonist morphine. The most common side effect is pain at the injection site when injected subcutaneously. In cats, moderate to severe response to injection was very commonly observed (in approximately one third of cats). In very rare cases, anaphylactic type reactions (allergic oedema, urticaria, erythema, collapse, dyspnoea, pale mucous membranes) may occur.

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 Prevomax 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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