10 December 2010
EMA/CVMP/498811/2010
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1]

Cimalgex

Cimicoxib

On 7 December 2010, 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 Cimalgex chewable tablets for dogs. Cimalgex tablets are intended for the treatment of pain and inflammation associated with osteoarthritis, and the management of peri-operative pain due to orthopaedic or soft tissue surgery, in dogs.

The applicant for this veterinary medicinal product is Vétoquinol SA.

The active substance of Cimalgex is cimicoxib (ATCvet code: QM01AH93), a non-steroidal anti-inflammatory drug (NSAID) of the coxib class which selectively inhibits the cyclooxygenase 2 enzyme (COX-2). The tablets are available in three different strengths, containing 8 mg, 30 mg or 80 mg cimicoxib.

The benefits of Cimalgex are its efficacy in the treatment of pain and inflammation in dogs.

The most common side effects are gastrointestinal adverse events (vomiting, diarrhoea). Although such side effects were very commonly reported they were usually mild and transient. On rare occasions, serious gastrointestinal disorders such as haemorrhage and ulcer formation have been noted, as have other adverse reactions including anorexia or lethargy.

The approved indication is: For the treatment of pain and inflammation associated with osteoarthritis, and the management of peri-operative pain due to orthopaedic or soft tissue surgery, in dogs.

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.

[1] Summaries of opinion are published without prejudice to the Commission Decision, which will normally be issued within 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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The CVMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit to risk balance for Cimalgex chewable tablets for dogs and therefore recommends the granting of the marketing authorisation.