16 April 2010
EMA/CVMP/139659/2010
Veterinary Medicines and Product Data Management

Committee for Medicinal Products for Veterinary Use

Summary of opinion*

Metacam EMEA/V/C/033/X/074

International non-proprietary name (INN): Meloxicam

On 13 April 2010, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion,** recommending to grant an extension of the marketing authorisation for the veterinary medicinal product Metacam to include a 2 mg/ml solution for injection for cats, intended for the alleviation of mild to moderate post-operative pain and inflammation following surgical procedures in cats, e.g. orthopaedic and soft tissue surgery. The Applicant for this veterinary medicinal product is Boehringer Ingelheim Vetmedica GmbH.

The active substance of Metacam is meloxicam, a non-steroidal anti-inflammatory drug (NSAID) of the oxicam class, ATCvet code: QM01AC06, which acts by inhibition of prostaglandin synthesis, thereby exerting anti-inflammatory, analgesic, anti-exudative and antipyretic effects. It reduces leukocyte infiltration into the inflamed tissue. To a minor extent it also inhibits collagen-induced thrombocyte aggregation.

The approved indication is the “alleviation of mild to moderate post-operative pain and inflammation following surgical procedures in cats, e.g. orthopaedic and soft tissue surgery”. Typical adverse reactions of Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) such as loss of appetite, vomiting, diarrhoea, faecal occult blood, apathy and renal failure have occasionally been reported. These adverse reactions are in most cases transient and disappear following termination of the treatment but in very rare cases may be serious or fatal. In very rare cases anaphylactoid reactions may occur and should be treated symptomatically.

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 Metacam 2 mg/ml solution for injection for cats and therefore recommends the extension of the marketing authorisation.

* Summaries of opinion are published without prejudice to the Commission Decision, which will normally be issued within 90 days from adoption of the Opinion.

** Applicants may appeal any CVMP opinion, provided they notify the EMEA in writing of their intention to appeal within 15 days of receipt of the opinion.

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