16 April 2010
EMA/CVMP/140057/2010
Veterinary Medicines and Product Data Management

Committee for Medicinal Products for Veterinary Use

Summary of opinion*

Metacam EMEA/V/C/033/X/079

International non-proprietary name (INN): Meloxicam

On 14 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 15 mg/ml oral suspension for pigs. 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, anti-exudative, analgesic and antipyretic effects. It reduces leukocyte infiltration into the inflamed tissue. To a minor extent it also inhibits collagen-induced thrombocyte aggregation. Meloxicam also has anti-endotoxic properties because it has been shown to inhibit production of thromboxane B_2 induced by *E. coli* endotoxin administration in pigs.

The approved indication is: "for use in non-infectious locomotor disorders to reduce the symptoms of lameness and inflammation. For adjunctive therapy in the treatment of puerperal septicaemia and toxaemia (Mastitis-Metritis-Agalactia syndrome MMA) with appropriate antibiotic therapy".

The product should not be used in pigs suffering from impaired hepatic, cardiac or renal function and haemorrhagic disorders, or where there is evidence of ulcerogenic gastrointestinal lesions or in case of hypersensitivity to the active substance or to any of the excipients.

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 15 mg/ml oral suspension for pigs 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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