17 September 2010
EMA/CVMP/140266/2010
Veterinary Medicine and Product Data Management

Committee for Medicinal Products for Veterinary Use

Summary of opinion*

Meloxoral EMEA/V/C/151

International Non-proprietary Name (INN): Meloxicam

On 14 September 2010, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion,** recommending to grant a marketing authorisation for the veterinary medicinal product Meloxoral 0.5 mg/ml oral suspension for Cats and Meloxoral 1.5 mg/ml oral suspension for Dogs, intended for the alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders in dogs and the alleviation of inflammation and pain in chronic musculo-skeletal disorders in cats. The Applicant for this veterinary medicinal product is LeVet B.V.

The active substance of Meloxoral 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 benefits of Meloxoral are the alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders in dogs and the alleviation of inflammation and pain in chronic musculo-skeletal disorders in cats. Typical adverse reactions of NSAIDs such as loss of appetite, vomiting, diarrhoea, faecal occult blood and apathy have occasionally been reported. These adverse reactions occur generally within the first treatment week and are in most cases transient and disappear following termination of the treatment but in very rare cases may be serious or fatal.

The approved indication is: “alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders in dogs and the alleviation of inflammation and pain in chronic musculo-skeletal disorders in cats.”

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

* 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 EMA in writing of their intention to appeal within 15 days of receipt of the opinion.

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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 Meloxoral 0.5 mg/ml oral suspension for cats and Meloxoral 1.5 mg/ml oral suspension for dogs and therefore recommends the granting of the marketing authorisation.