The European Medicines Agency
Veterinary Medicines and Inspections

London, 15 January 2010
Doc. Ref.: EMA/CVMP/826131/2009

COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE
SUMMARY OF OPINION*
MELOXIDYL

International Non-proprietary Name (INN):
Meloxicam

On 13 January 2010 the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion,** recommending the extension of the marketing authorisation for the veterinary medicinal product Meloxidyl. The Applicant for this veterinary medicinal product is Ceva Santé Animale.

Meloxidyl is currently authorised as 1.5 mg/ml oral suspension for dogs and 5mg/ml solution for injection for dogs and cats. The new extension concerns cattle, pigs and horses, and a new strength 20 mg/ml solution for injection. The active substance of Meloxidyl is Meloxicam, a non-steroidal anti-inflammatory drug (NSAID), ATCvet code: QM01AC06.

The approved indications in cattle are for use in acute respiratory infection with appropriate antibiotic therapy to reduce clinical signs, for use in diarrhoea in combination with oral re-hydration therapy to reduce clinical signs in calves of over one week of age and young, non-lactating cattle and for adjunctive therapy in the treatment of acute mastitis, in combination with antibiotic therapy.

The approved indications in pigs are for use in non-infectious locomotor disorders to reduce the symptoms of lameness and inflammation and for adjunctive therapy in the treatment of puerperal septicaemia and toxaemia (mastitis –metritis –agalactia syndrome) with appropriate antibiotic therapy.

The approved indications in horses are for use in the alleviation of inflammation and relief of pain in both acute and chronic musculo-skeletal disorders and for the relief of pain associated with equine colic.

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 Meloxidyl and therefore recommends the granting of the extension of the marketing authorisation.

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* 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 European Medicines Agency in writing of their intention to appeal within 15 days of receipt of the opinion.

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