EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Veterinary Medicine and Product Data Management

Committee for Medicinal Products for Veterinary Use

Summary of opinion*

Meloxidyl

International Non-proprietary Name (INN): Meloxicam

On 16 June 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 5 mg/ml solution for injection for dogs and cats, as well as 20 mg/ml solution for injection for cattle, pigs and horses. The new extension concerns a new strength 0.5 mg/ml oral suspension for cats. The active substance of Meloxidyl is meloxicam, a non-steroidal anti-inflammatory drug (NSAID), ATCvet code: QM01AC06.

The approved indication in cats is for use in the alleviation of inflammation and pain in chronic musculo-skeletal disorders.

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.

* 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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