European Medicines Agency
Veterinary Medicines and Inspections

London, 17 October 2008
Doc. Ref.: EMEA/CVMP/512781/2008

COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE

ACTICAM

International Non-proprietary Name (INN):
MELOXICAM

On 15 October 2008, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion,** recommending to grant a marketing authorisation for the veterinary medicinal product Acticam, 1.5 mg/ml Oral suspension for the alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders. A positive Opinion was also adopted for Acticam 5 mg/ml solution for injection. The Applicant for this veterinary medicinal product is Omnipharm Ltd.

The active substance of Acticam is meloxicam (ATCvet Code: QM01AC060) which belongs to a class of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). Meloxicam acts by inhibition of prostaglandin synthesis.

The benefits of Acticam are its ability to reduce the responses to prostaglandin synthesis such as those triggering inflammation, pain and exudation.

Occasional side effects are those seen with NSAIDs, such as loss of appetite, vomiting, diarrhoea, blood appearing in the stools and apathy (lack of vitality).

The approved indication for Acticam 1.5 mg/ml oral suspension is for Alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders in dogs. The approved indication in dogs for Acticam 5 mg/ml solution for injection is alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders and the reduction of post-operative pain and inflammation following orthopaedic and soft tissue surgery. In cats the product is indicated for the reduction of post-operative pain after ovariohysterectomy and minor soft tissue surgery.

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 the data submitted, considers that there is a favourable benefit to risk balance for Acticam and therefore recommends the granting of the marketing authorisation

** 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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