European Medicines Agency
*Veterinary Medicines and Inspections*

London, 17 July 2009
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**COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE**
**SUMMARY OF OPINION***
**RHEUMOCAM**

International Non-proprietary Name (INN):
Meloxicam

On 15 July 2009, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion,** recommending to extend the marketing authorisation for the veterinary medicinal product Rheumocam to include 1 mg and 2.5 mg chewable tablets for dogs, intended for the alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders. The Applicant for this veterinary medicinal product is Chanelle Pharmaceuticals Manufacturing Limited.

The active substance of Rheumocam is Meloxicam, an anti-inflammatory and anti-rheumatic product, non-steroids (oxicams), ATCvet Code QMO1AC06 which acts by inhibition of prostaglandin synthesis, thereby exerting anti-inflammatory, analgesic, anti-exudative and anti-pyretic effects.

The benefits of Rheumocam are the alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders. The most common side effects are typical adverse reactions of non-steroidal anti-inflammatory drugs such as loss of appetite, vomiting, diarrhoea, faecal occult blood, apathy and renal failure have occasionally been reported.

The approved indication is: “alleviation of inflammation and pain in both acute and 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 Rheumocam 1 mg and 2.5 mg chewable tablets for dogs and therefore recommends the extension of the marketing authorisation accordingly.

* 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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