11 November 2011
EMA/CVMP/765011/2011
Committee for Medicinal Products for Veterinary Use

Post authorisation summary of opinion*

Rheumocam

International non-proprietary name (INN): Meloxicam

On 8-10 November 2011, 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 Rheumocam. The applicant for this veterinary medicinal product is Chanelle Pharmaceuticals Manufacturing Limited.

Rheumocam is currently authorised as a chewable tablet for dogs, as an oral suspension for dogs and horses and as a 20 mg/ml solution for injection for cattle, pigs and horses. The new extension concerns a 5 mg/ml solution for injection for use in dogs and cats.

The active substance of Rheumocam is meloxicam, an anti-inflammatory and anti-rheumatic product, non-steroids (oxicams) ATCvet code: QM01AC06.

The new presentations will be available as 10 ml, 20 ml and 100 ml pack sizes and are to be administered in dogs by subcutaneous or intravenous use and in cats by subcutaneous use.

The most common side effects are loss of appetite, vomiting, diarrhoea, faecal occult blood and apathy have occasionally been reported. These side effects 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. In very rare cases anaphylactoid reactions may occur and should be treated symptomatically.

The approved indications are in dogs the 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 it will be used in 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

* 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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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 and therefore recommends the granting of the extension of the marketing authorisation.[***]

[***] Marketing authorisation under exceptional circumstances refers to the fact that in exceptional circumstances an authorisation may be granted subject to certain specific obligations, to be reviewed annually.