14 September 2012
EMA/CVMP/396534/2012
Committee for Medicinal Products for Veterinary Use

Post authorisation summary of opinion*

Rheumocam

International non-proprietary name (INN): Meloxicam

On 11-13 September 2012, 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, as a 20 mg/ml solution for injection for cattle, pigs and horses and as 5 mg/ml solution for injection for use in dogs and cats. The new extension concerns a 5 mg/ml solution for injection for use in cattle and pigs.

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 20 ml, 50 ml and 100 ml pack sizes and are to be administered in cattle by subcutaneous or intravenous use and in pigs by intramuscular use. The most common side effects are a slight transient swelling at the injection site.

The approved indications are:

Cattle:

For use in acute respiratory infection with appropriate antibiotic therapy to reduce clinical signs in cattle. 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.

Pigs:

For use in non-infectious locomotor disorders to reduce the symptoms of lameness and inflammation. For the relief of post operative pain associated with minor soft tissue such as castration.

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