12 November 2010
EMA/CVMP/147814/2010
Committee for Medicinal Products for Veterinary Use

Post authorisation summary of opinion*

Rheumocam

International non-proprietary name (INN): Meloxicam

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

Rheumocam is currently authorised as an oral suspension and chewable tablet for dogs. This extension concerns a new 15 mg/ml oral suspension for horses.

The active substance of Rheumocam is meloxicam, a non-steroidal anti-inflammatory drug (NSAID) of the oxicam class (ATC vet code: QM01AC06).

The new presentations will be available as a 15 mg/ml oral suspension in 100 and 250 ml bottles with measuring syringes and are to be administered orally either mixed with food or directly into the mouth.

The most common side effects observed in clinical trials involved isolated cases of adverse reactions typically associated with NSAIDs (slight urticaria, diarrhoea). Symptoms were reversible.

The approved indication is: “Alleviation of inflammation and relief of pain in both acute and chronic musculo-skeletal disorders in horses.”

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 15 mg/ml oral suspension for horses 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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