15 July 2011
EMA/CVMP/534720/2010
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1]

Recocam

International non-propiretary name (INN): Meloxicam

On 14 July 2011, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion,[2] recommending the granting of a marketing authorisation for the generic veterinary medicinal product Recocam, a meloxicam 20 mg/ml solution for injection, intended for cattle, pigs and horses. The applicant for this veterinary medicinal product is CF Pharma Limited.

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

The benefits of Recocam are the alleviation of inflammation and relief of pain in the approved indications. The most common side effects are a slight transient swelling at the injection site following subcutaneous administration in cattle and in horses a 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. For adjunctive therapy in the treatment of acute mastitis, in combination with antibiotic therapy.

Pigs: For use in non-infectious locomotor disorders to reduce the symptoms of lameness and inflammation. For adjunctive therapy in the treatment of puerperal septicaemia and toxaemia (mastitis-metritis-agalactia syndrome) with appropriate antibiotic therapy.

Horses: For use in the alleviation of inflammation and relief of pain in both acute and chronic musculoskeletal disorders. For the relief of pain associated with equine colic".

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

[1] Summaries of opinion are published without prejudice to the Commission Decision, which will normally be issued within 90 days from adoption of the opinion.
[2] 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 Recocam and therefore recommends the granting of the marketing authorisation.