19 July 2013
EMA/CVMP/384390/2013
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (post-authorisation)

Melovem

International non-proprietary name (INN): meloxicam

On 18 July 2013, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion[2] recommending the extension of the marketing authorisation for the veterinary medicinal product Melovem. The applicant for this veterinary medicinal product is Dopharma Research B.V.

Melovem is currently authorised as a 5 mg/ml solution for injection for use in cattle and pigs. The new extension concerns a 20 mg/ml solution for injection in cattle, pigs and horses.

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

The benefits of Melovem 20 mg/ml solution for injection in cattle, pigs and horses result from the anti-inflammatory effect of meloxicam. It is beneficial in reducing clinical signs associated with respiratory disease in cattle, diarrhoea in calves and young non-lactating cattle and acute mastitis in cattle; non-infectious locomotor disorders in pigs and puerperal septicaemia and toxaemia in sows; and acute and chronic musculoskeletal disorders in horses.

The most common side effect is 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. For adjunctive therapy in the treatment of acute mastitis, in combination with antibiotic therapy.

[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.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
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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 musculo-skeletal 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 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 Melovem 20 mg/ml solution for injection for cattle, pigs and horses and therefore recommends the granting of the extension of the marketing authorisation.