17 June 2016
EMA/CVMP/371866/2016
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (post-authorisation)

Metacam

International non-proprietary name (INN): meloxicam

On 16 June 2016, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion[2], recommending the granting of a marketing authorisation for the veterinary medicinal product Metacam, solution for injection, intended for:

- 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; for the relief of post-operative pain following dehorning in calves.
- 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.

The applicant for this veterinary medicinal product is Boehringer Ingelheim Vetmedica GmbH.

Metacam is a non steroidal anti-inflammatory medicinal product containing meloxicam (ATCvet code QM01AC06) as active substance, which acts by inhibition of prostaglandin synthesis.

The extension concerns the addition of a new administration route (subcutaneous) for meloxicam 40 mg/ml solution for injection, for the existing target species cattle. The benefit of the added route of administration (subcutaneous) of Metacam is the reduced volume needed for administration. The most common side effects are a slight transient painless swelling at the injection site.

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

[1] Summaries of opinion are published without prejudice to the Commission Decision, which will normally be issued 67 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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favourable benefit-risk balance for Metacam and therefore recommends the granting of the marketing authorisation.