13 February 2015
EMA/CVMP/736376/2014
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (post-authorisation)

Metacam

International non-proprietary name (INN): meloxicam

On 12 February 2015, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted an opinion[2] recommending the granting of an extension to the terms of the marketing authorisation for the veterinary medicinal product Metacam. The marketing authorisation holder for this veterinary medicinal product is Boehringer Ingelheim Vetmedica GmbH.

Metacam is currently authorised as solution for injection for cats, dogs, cattle, pigs and horses, as oral suspension for cats, dogs, pigs and horses, and as chewable tablets for dogs.

The extension concerns the addition of a new strength, meloxicam 40 mg/ml solution for injection, for the existing target species cattle and horses. The route of administration is intravenous.

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.

The CVMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit to risk balance for Metacam 40 mg/ml solution for injection for cattle and horses and therefore recommends the granting of the extension of the marketing authorisation.

[1] Summaries of opinion are published without prejudice to the Commission Decision.
[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.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact