



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

19 February 2021
EMA/CVMP/92881/2021
Committee for Medicinal Products for Veterinary Use

Summary of opinion¹ (post-authorisation)

Emdocam

International non-proprietary name (INN): meloxicam

On 17 February 2021, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion², recommending the granting of an extension to the terms of the marketing authorisation for the veterinary medicinal product Emdocam. The marketing authorisation holder for this veterinary medicinal product is Emdoka BVBA.

Emdocam is currently authorised as a solution for injection for cattle, pigs and horses. The active substance of Emdocam is meloxicam, a non-steroidal anti-inflammatory drug (NSAID) of the oxicam class (ATCvet code: QM01AC06). The extension concerns the addition of a new strength 15 mg/ml and new pharmaceutical form - oral suspension for horses. The 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 are described in the updated summary of product characteristics (SPC), for which an updated version reflecting the changes will be published in the revised European public assessment report (EPAR) and will be available in all official European Union languages after the extension to the marketing authorisation has been granted by the European Commission.

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.

