19 February 2021
EMA/CVMP/92879/2021
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (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 opinion[2], 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 solution for injection. 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 5 mg/ml solution for injection for cattle, pigs and for the new target species dogs and cats. The indications for the new target species, dogs and cats, are:

Dogs:

Alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders. Reduction of post-operative pain and inflammation following orthopaedic and soft tissue surgery.

Cats:

Reduction of post-operative pain after ovariohysterectomy and minor soft tissue surgery.

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.

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