8 September 2023
EMA/CVMP/386093/2023
Committee for Veterinary Medicinal Products

Summary of opinion[1] (initial authorisation)

Loxitab

International non-proprietary name (INN): meloxicam

On 5-7 September, the Committee for Veterinary Medicinal Products (CVMP) adopted a positive opinion[2], recommending the granting of a marketing authorisation for the veterinary medicinal product Loxitab 1 mg and 2.5 mg tablets for dogs. The applicant for this veterinary medicinal product is CP-Pharma Handelsgesellschaft mbH.

Loxitab is a medicinal product containing meloxicam (ATCvet code QM01AC06) as active substance, a non-steroidal anti-inflammatory drug (NSAID) of the oxicam class which acts by inhibition of prostaglandin synthesis, thereby exerting anti-inflammatory, analgesic, anti-exudative and antipyretic effects.

Loxitab is a hybrid of Metacam 1.5 mg/ml oral suspension for dogs. Metacam has been authorised in the EU since 7 January 1998. Studies have demonstrated the satisfactory quality of Loxitab, and its bioequivalence to the reference product Metacam 1.5 mg/ml oral suspension for dogs.

The full indication is: alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders in dogs.

Detailed conditions for the use of this product are described in the summary of product characteristics (SPC) which will be published in the Union Product Database (UPD) 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-risk balance for Loxitab and therefore recommends the granting 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.

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