13 September 2024
EMA/CVMP/417587/2024
Committee for Veterinary Medicinal Products

Summary of opinion[1] (initial authorisation)

ArthriCox

International non-proprietary name (INN): Firocoxib

On 12 September 2024, the Committee for Veterinary Medicinal Products (CVMP) adopted a positive opinion[2], recommending the granting of a marketing authorisation for the veterinary medicinal product ArthriCox 57 mg and 227 mg chewable tablets for dogs. The applicant for this veterinary medicinal product is Chanelle Pharmaceuticals Manufacturing Ltd.

ArthriCox is a medicinal product containing firocoxib (ATCvet code: QM01AH90) as active substance. Firocoxib is a non-steroidal anti-inflammatory drug (NSAID) belonging to the coxib group which acts by selective inhibition of cyclooxygenase-2 (COX-2)-mediated prostaglandin synthesis displaying as a result analgesic, anti-inflammatory and antipyretic properties.

ArthriCox is a generic of Previcox, which has been authorised in the EU since 13 September 2004. Studies have demonstrated the satisfactory quality of ArthriCox and its bioequivalence to the reference product Previcox.

The target species is dogs and the full indication is for the relief of pain and inflammation associated with osteoarthritis and for the relief of post-operative pain and inflammation associated with soft-tissue, orthopaedic and dental surgery.

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 ArthriCox 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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