17 June 2022
EMA/CVMP/563847/2022
Committee for Veterinary Medicinal Products

Summary of opinion[1] (initial authorisation)

Coxatab

International non-proprietary name (INN): firocoxib

On 15 June 2022 the Committee for Veterinary Medicinal Products (CVMP) adopted a positive opinion[2], recommending the granting of a marketing authorisation for the veterinary medicinal product Coxatab chewable tablets for dogs. The applicant for this veterinary medicinal product is CP-Pharma Handelsgesellschaft mbH.

Coxatab is medicinal product containing firocoxib (ATCvet code QM01AH90) as active substance which 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.

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

The full indication is:

- For the relief of pain and inflammation associated with osteoarthritis in dogs.
- For the relief of post-operative pain and inflammation associated with soft-tissue, orthopaedic and dental surgery 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 European public assessment report (EPAR) 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 Coxatab and therefore recommends the granting of the marketing authorisation.

[1] Summaries of opinion are published without prejudice to the Commission Decision, which will normally be issued 67 days from adoption of the opinion.
[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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