19 February 2021
EMA/CVMP/65023/2021
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

Daxocox

International non-proprietary name (INN): enflicoxib

On 17 February 2021, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion[2], recommending the granting of a marketing authorisation for the veterinary medicinal product Daxocox tablets for dogs. The applicant for this veterinary medicinal product is Ecuphar NV.

Daxocox is an anti-inflammatory medicinal product containing enflicoxib (ATCvet code: QM01AH95) as active substance, which is a non-steroidal anti-inflammatory drug belonging to the coxib class and acting by selective inhibition of the enzyme cyclooxygenase-2.

The benefits of Daxocox are its efficacy in the treatment of pain and inflammation associated with osteoarthritis (or degenerative joint disease) in dogs. The most common side effects are vomiting, soft faeces and/or diarrhoea; apathy, loss of appetite, haemorrhagic diarrhoea or gastrointestinal ulceration have also been reported in uncommon cases.

The full indication is: “for the treatment of pain and inflammation associated with osteoarthritis (or degenerative joint disease) 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 Daxocox 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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