21 June 2024
EMA/CVMP/273005/2024
Committee for Veterinary Medicinal Products (CVMP)

Summary of opinion[1] (post-authorisation)

Daxocox

International non-proprietary name (INN): enflicoxib

On 19 June 2024, the Committee for Veterinary Medicinal Products (CVMP) adopted a positive opinion[2], recommending the granting of a group of variations to the terms of the marketing authorisation for the veterinary medicinal product Daxocox. The marketing authorisation holder for this veterinary medicinal product is Ecuphar NV.

Daxocox is currently authorised as tablets for use in dogs. The variation concerns the addition of two new tablet strengths (140 and 200 mg) to the existing range and the amendment of the dosing table for the currently approved tablet strengths (15, 30, 45, 70 and 100 mg).

Detailed conditions for the use of this product are described in the summary of product characteristics (SPC), for which an updated version reflecting the changes will be published in the Union Product Database (UPD) and will be available in all official European Union languages after the variation 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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