8 December 2023
EMA/CVMP/566235/2023
Committee for Veterinary Medicinal Products (CVMP)

Summary of opinion[1] (post-authorisation)

Bravecto

International non-proprietary name (INN): fluralaner

On 5-7 December 2023, the Committee for Veterinary Medicinal Products (CVMP) adopted a positive opinion[2], recommending the granting of a variation to the terms of the marketing authorisation for the veterinary medicinal product Bravecto. The marketing authorisation holder for this veterinary medicinal product is Intervet International B.V.

Bravecto is currently authorised as chewable tablets and spot-on solutions for dogs and cats. The variation concerns the addition of a new pharmaceutical form, 150 mg/ml powder and solvent for suspension for injection, for dogs. This new pharmaceutical form also introduces a new route of administration.

Detailed conditions for the use of this product are described in the updated 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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