10 December 2021
EMA/CVMP/696735/2021
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (post-authorisation)

Bravecto

International non-proprietary name (INN): fluralaner

On 9 December 2021, the Committee for Medicinal Products for Veterinary Use (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 solution for use in dogs and as spot-on solution for use in cats. The variation concerns the addition of a new therapeutic indication for Bravecto chewable tablets for dogs: for reduction of the risk of infection with *Babesia canis canis* via transmission by *Dermacentor reticulatus* for up to 12 weeks. The effect is indirect due to product's activity against the vector.

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 revised European public assessment report (EPAR) 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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