17 June 2022
EMA/CVMP/294601/2022
Committee for Veterinary Medicinal Products

Summary of opinion[1] (post-authorisation)

Bravecto

International non-proprietary name (INN): fluralaner

On 15 June 2022, 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 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 grouped variation is to add two new therapeutic indications for Bravecto chewable tablets for dogs: for persistent tick killing activity from 7 days to 12 weeks after treatment for *Ixodes hexagonus* and for reduction of the risk of infection with *Dipylidium caninum* via transmission by *Ctenocephalides felis* for up to 12 weeks.

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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