EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

13 June 2025
EMA/CVMP/187220/2025
Committee for Veterinary Medicinal Products

**Summary of opinion[1] (initial authorisation)**

# Bravecto CombiUNO

## International non-proprietary name (INN): Fluralaner / Milbemycin oxime

On 12 June 2025, the Committee for Veterinary Medicinal Products (CVMP) adopted a positive opinion[2], recommending the granting of a marketing authorisation for the veterinary medicinal product Bravecto CombiUNO chewable tablets intended for dogs. The applicant for this veterinary medicinal product is Intervet International B.V.

Bravecto CombiUNO is an antiparasitic medicinal product containing fluralaner and milbemycin oxime as active substances (ATCvet code: QP54AB51). Both substances exert parasiticidal activity by interacting with ligand-gated ion channels in the nervous system of various parasites such as insects, acari and helminths.

The benefit of Bravecto CombiUNO is its efficacy in dogs with, or at risk from, mixed parasitic infestations by ticks or fleas, gastrointestinal nematodes, lungworm and/or heartworm.

The most common side effect is emesis.

The full indication is: "*For dogs with, or at risk from, mixed parasitic infestations by ticks or fleas, gastrointestinal nematodes, lungworm and/or heartworm. The veterinary medicinal product is exclusively indicated when used against ticks or fleas and gastrointestinal nematodes at the same time. The veterinary medicinal product also provides concurrent efficacy for the prevention of heartworm disease and angiostrongylosis.*

*For the treatment of tick and flea infestations on dogs providing immediate and persistent flea (Ctenocephalides felis and C. canis) killing activity and immediate and persistent tick (Dermacentor reticulatus, Ixodes hexagonus, I. ricinus, and Rhipicephalus sanguineus) killing activity for 1 month.*

*The veterinary medicinal product can be used as part of a treatment strategy for the control of flea allergy dermatitis (FAD).*

*For reduction of the risk of infection with Babesia canis canis via transmission by D. reticulatus for 1*

[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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*month. The effect is indirect due to the product's activity against the vector.*

*For reduction of the risk of infection with Dipylidium caninum via transmission by C. felis for 1 month. The effect is indirect due to the product's activity against the vector.*

*Treatment of infections with gastrointestinal nematodes of the following species: roundworms (immature adult (L5) and adult stages of Toxocara canis, and adult stages of Toxascaris leonina), hookworms (immature adult (L5) and adult stages of Ancylostoma caninum) and whipworm (adult stage of Trichuris vulpis).*

*Prevention of heartworm disease (Dirofilaria immitis).*

*Prevention of angiostrongylosis (by reduction of the level of infection with immature adult (L5) and adult stages of Angiostrongylus vasorum) with monthly administration.*"

Detailed conditions for the use of this product are described in the summary of product characteristics (SPC), which will be published in the Union Product Database (UPD) 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 Bravecto CombiUNO and, therefore, recommends the granting of the marketing authorisation.