16 May 2025
EMA/CVMP/149237/2025
Committee for Veterinary Medicinal Products

Summary of opinion[1] (initial authorisation)

Fluralaner Intervet

International non-proprietary name (INN): Fluralaner

On 15 May 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 Fluralaner Intervet, chewable tablets, intended for dogs. The applicant for this veterinary medicinal product is Intervet International B.V.

Fluralaner Intervet is an ectoparasiticide medicinal product containing fluralaner (ATCvet code QP53BE02) as active substance, with inhibitory activity on GABA- and glutamate-gated chloride channel located in nervous system of invertebrates, preventing the postsynaptic uptake of chloride ions by GABA- and glutamate-gated ion channels and thus resulting in depolarization, paralysis and death of the target parasite.

The benefits of Fluralaner Intervet are its efficacy for the treatment of tick and flea infestations in dogs, its use as part of a treatment strategy for the control of flea allergy dermatitis (FAD), and for the reduction of the risk of infection with *Babesia canis canis* and with *Dipylidium caninum* via the product's activity against their respective vectors.

The most common side effects are digestive tract disorders like anorexia, hypersalivation, diarrhoea and emesis (vomiting).

The full indication is: For the treatment of tick and flea infestations in dogs. This veterinary medicinal product is a systemic insecticide and acaricide that provides:

- immediate and persistent flea (*Ctenocephalides canis* and *C. felis*) killing activity for 1 month,
- 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 month. The effect is indirect due to the veterinary medicinal product's activity against the vector.

[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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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 veterinary medicinal product's activity against the vector.

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 Fluralaner Intervet and therefore recommends the granting of the marketing authorisation.