15 January 2026
EMA/CVMP/1734/2026
Committee for Veterinary Medicinal Products

Summary of opinion[1] (initial authorisation)

Lotilaner/Milbemycin Elanco

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

On 15 January 2026, the Committee for Veterinary Medicinal Products (CVMP) adopted a positive opinion[2], recommending the granting of a marketing authorisation for the veterinary medicinal product Lotilaner/Milbemycin Elanco, chewable tablet, intended for dog. The applicant for this veterinary medicinal product is Elanco GmbH.

Lotilaner/Milbemycin Elanco is an antiparasitic veterinary medicinal product (ATCvet code: QP54AB51) containing lotilaner and milbemycin oxime as active substances, which belong to the isoxazoline and macrocyclic lactones class of parasiticides, respectively. Both act by interacting with chloride channels in the nervous and/or muscular system of invertebrates, resulting in the death of various parasites such as insects, acari and helminths.

The application for Lotilaner/Milbemycin Elanco was an informed consent application. In an informed consent application, reference is made to an authorised medicine where the marketing authorisation holder of the reference medicine has given consent to the use of their dossier in the application procedure. The reference product for Lotilaner/Milbemycin Elanco is Credelio Plus (EU/2/21/271).

The full indication is:

For use in dogs with, or at risk from, mixed infestations/infections by ticks, fleas, gastrointestinal nematodes, heartworm and/or lungworm.

This veterinary medicinal product is only indicated for use when treatment against ticks/fleas/mites and gastrointestinal nematodes or the treatment against ticks/fleas/ mites and prevention of heartworm disease/angiostrongylosis is indicated at the same time.

Ectoparasites

For the treatment of tick *(Dermacentor reticulatus, Ixodes ricinus, Rhipicephalus sanguineus* and *I. hexagonus*) and flea (*Ctenocephalides felis* and *C. canis*) infestations in dogs.

[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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This veterinary medicinal product provides immediate and persistent killing activity for 1 month for ticks and fleas.

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 *Dermacentor reticulatus* for one month. The effect is indirect due to the activity of the veterinary medicinal product against the vector.

For the treatment of demodicosis (caused by *Demodex canis*).

For the treatment of sarcoptic mange (*Sarcoptes scabiei var. canis*).

Gastrointestinal Nematodes
Treatment of gastrointestinal nematodes: hookworm (L4, immature adult (L5) and adult *Ancylostoma caninum*), roundworms (L4, immature adult (L5) and adult *Toxocara canis*, and adult *Toxascaris leonina*) and whipworm (adult *Trichuris vulpis*).

Heartworm
Prevention of heartworm disease (*Dirofilaria immitis*).

Lungworm
Prevention of angiostrongylosis by reduction of the level of infection with immature adult (L5) and adult stages of *Angiostrongylus vasorum* (lungworm) 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 considers that there is a favourable benefit-risk balance for Lotilaner/Milbemycin Elanco and therefore recommends the granting of the marketing authorisation.