19 February 2021
EMA/CVMP/65055/2021
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

Credelio Plus

International non-proprietary name (INN): lotilaner / milbemycin oxime

On 17 February 2021, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion[2], recommending the granting of a marketing authorisation for the veterinary medicinal product Credelio Plus chewable tablets intended for use in dogs. The applicant for this veterinary medicinal product is Elanco GmbH.

Credelio Plus 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 benefits of Credelio Plus are its efficacy against tick and flea infestations as well as gastrointestinal nematode (hookworm, roundworm and whipworm) infections, in addition to its efficacy in the prevention of heartworm and lungworm disease (angiostrongylosis). The most common side effects are transient gastrointestinal signs (diarrhoea and vomiting) as well as transient anorexia, muscle tremors, lethargy, pruritus and changes in behaviour.

The full indication is:

"For use in dogs with, or at risk from, mixed infestations/infections of ticks, fleas, gastrointestinal nematodes, heartworm and/or lungworm. This veterinary medicinal product is intended for use where treatment and/or prevention of two or more of the indications below is required concurrently.

Ticks and Fleas

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, which will normally be issued 67 days from adoption of the opinion.
[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).

Gastrointestinal Nematodes

Treatment of gastrointestinal nematodes: hookworm (L4, immature adult (L5) and adult *Ancylostoma caninum*), roundworms (L4, immature adult (L5) and adult *Toxocara canis*, 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 European public assessment report (EPAR) 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 Credelio Plus and therefore recommends the granting of the marketing authorisation.