



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

17 February 2017
EMA/CVMP/49053/2017
Committee for Medicinal Products for Veterinary Use

Summary of opinion¹ (initial authorisation)

Credelio

International non-proprietary name (INN): lotilaner

On 16 February 2017, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion², recommending the granting of a marketing authorisation for the veterinary medicinal product Credelio, chewable tablet, intended for the treatment of flea and tick infestations in dogs. The applicant for this veterinary medicinal product is Elanco Europe Ltd.

Credelio is an antiparasitic medicinal product containing lotilaner (ATCvet code QP53BE04) as active substance. Lotilaner is an ectoparasiticide from the isoxazoline class, and it is a potent inhibitor of gamma-aminobutyric acid (GABA)-gated chloride channels resulting in the rapid death of ticks and fleas.

The benefits of Credelio are its efficacy in the treatment of tick (*Dermacentor reticulatus*, *Ixodes hexagonus*, *Ixodes ricinus* and *Rhipicephalus sanguineus*) and flea (*Ctenocephalides felis* and *Ctenocephalides canis*) infestations in dogs and Credelio's use as part of a treatment strategy for the control of flea allergy dermatitis (FAD). Credelio is generally well tolerated at the recommended dose.

Detailed conditions for the use of this product will be 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 and therefore recommends the granting of the marketing authorisation.

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.

