

21 January 2022 EMA/CVMP/11507/2022 Committee for Medicinal Products for Veterinary Use

Summary of opinion¹ (post-authorisation)

Credelio

International non-proprietary name (INN): lotilaner

On 19 January 2022, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion², recommending the granting of a variation to the terms of the marketing authorisation for the veterinary medicinal product Credelio. The marketing authorisation holder for this veterinary medicinal product is Elanco GmbH.

Credelio is currently authorised as chewable tablets for the treatment of flea and tick infestations in dogs and cats. The variation concerns the addition of a new therapeutic indication for the treatment of demodicosis (caused by *Demodex canis*) in dogs.

Detailed conditions for the use of this product are described in the summary of product characteristics (SPC), for which an updated version reflecting the changes will be published in the revised European public assessment report (EPAR) and will be available in all official European Union languages after the variation to the marketing authorisation has been granted by the European Commission.

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.



¹ Summaries of opinion are published without prejudice to the Commission Decision.