EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 April 2018
EMA/CVMP/175952/2018
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (post-authorisation)

Credelio

International non-proprietary name (INN): lotilaner

On 19 April 2018, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion[2], recommending the granting of an extension to the terms of the marketing authorisation for the veterinary medicinal product Credelio. The marketing authorisation holder for this veterinary medicinal product is Elanco Europe Ltd.

Credelio is currently authorised as chewable tablet for dogs. This extension application is to add further, lower tablet strengths of 12 mg and 48 mg for the treatment of flea and tick infestations in a new target species, cats.

Detailed conditions for the use of this product are described in the updated 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 extension to the marketing authorisation has been granted by the European Commission.

[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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