7 November 2025
EMADOC-1700519818-2563727
Committee for Veterinary Medicinal Products (CVMP)

Summary of opinion[1] (post-authorisation)

Credelio, Lotimax, Credelio Plus

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

On 6 November 2025, the Committee for Veterinary Medicinal Products (CVMP) adopted a positive opinion[2], recommending the granting of a group of variations requiring assessment to the terms of the marketing authorisation following a worksharing procedure for the veterinary medicinal products Credelio, Lotimax and Credelio Plus. The marketing authorisation holder for these veterinary medicinal products is Elanco GmbH.

Credelio is currently authorised as chewable tablets for use in dogs and cats, while Lotimax and Credelio Plus are authorised as chewable tablets for use in dogs. The grouped variation concerns change(s) to therapeutic indication(s) in dogs - addition of a new therapeutic indication or modification of an approved one: 'for the treatment of sarcoptic mange (*Sarcoptes scabiei* var. *canis*)' and '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.' Additionally, the product information for all three products has been aligned with version 9.1 of the QRD template.

Detailed conditions for the use of these products are described in the summary of product characteristics (SPC), for which updated versions reflecting the changes will be published in the Union Product Database (UPD) and will be available in all official European Union languages after the variation 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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