17 February 2023
EMA/CVMP/42347/2023
Committee for Veterinary Medicinal Products (CVMP)

Summary of opinion[1] (post-authorisation)

Lotilaner Elanco

International non-proprietary name (INN): lotilaner

On 15 February 2023, the Committee for Veterinary Medicinal Products (CVMP) adopted a positive opinion[2], recommending the granting of a variation to the terms of the marketing authorisation for the veterinary medicinal product Lotilaner Elanco. The marketing authorisation holder for this veterinary medicinal product is Elanco GmbH.

Lotilaner Elanco is currently authorised as chewable tablets for use in dogs and cats. The variation concerns the change of the classification from 'subject to prescription' to 'not subject to veterinary prescription'.

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.

[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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