15 March 2024
EMA/CVMP/99608/2024
Committee for Veterinary Medicinal Products

Summary of opinion[1] (initial authorisation)

Lotimax

International non-proprietary name (INN): lotilaner

On 12-13 March 2024, the Committee for Veterinary Medicinal Products (CVMP) adopted a positive opinion[2], recommending the granting of a marketing authorisation for the veterinary medicinal product Lotimax, Chewable tablet, intended for use in dogs. The applicant for this veterinary medicinal product is Elanco GmbH.

Lotimax is an antiparasitic medicinal product containing lotilaner (ATCvet code QP53BE04) as active substance, which is a pure enantiomer from the isoxazoline class that acts as an inhibitor of gamma–aminobutyric acid (GABA)-gated chloride channels, resulting in death of target parasites.

The application for Lotimax was an informed consent application. In an informed consent application, reference is made to an authorised medicine where the marketing authorisation holder of the reference medicine has given consent to the use of their dossier in the application procedure. The reference product for Lotimax is Credelio.

The full indication is:
Dogs:

For the treatment of flea and tick infestations in dogs.
This veterinary medicinal product provides immediate and persistent killing activity for 1 month for fleas (*Ctenocephalides felis* and *C. canis*) and ticks (*Rhipicephalus sanguineus, Ixodes ricinus, I. hexagonus* and *Dermacentor reticulatus*).
Fleas and ticks must attach to the host and commence feeding in order to be exposed to the active substance.
The veterinary medicinal product can be used as part of a treatment strategy for the control of flea allergy dermatitis (FAD).
For the treatment of demodicosis (caused by *Demodex canis*).

Detailed conditions for the use of this product are described in the summary of product characteristics

[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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(SPC) which will be published in the Union Product Database (UPD) 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 for the reference product Credelio and the informed consent accepted for this application, considers that there is a favourable benefit-risk balance for Lotimax and therefore recommends the granting of the marketing authorisation.