11 October 2024
EMA/CVMP/446484/2024
Committee for Veterinary Medicinal Products (CVMP)

Summary of opinion[1] (post-authorisation)

Eluracat

International non-proprietary name (INN): capromorelin tartrate

On 10 October 2024, the Committee for Veterinary Medicinal Products (CVMP) adopted a positive opinion[2], recommending the granting of a group of variations to the terms of the marketing authorisation for the veterinary medicinal product Eluracat. The marketing authorisation holder for this veterinary medicinal product is Elanco GmbH.

Eluracat is currently authorised as oral solution for use in cats. This grouped variation is to implement the outcome of the MAH's signal management process and to move the warning for use of the product in cats with hypersomatotropism (acromegaly) from the special precautions section of the product information to the contraindications section.

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 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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