

22 May 2023 EMA/CVMP/194243/2023 Committee for Veterinary Medicinal Products

Summary of opinion¹ (initial authorisation)

Eluracat

International non-proprietary name (INN): capromorelin tartrate

On 15-16 May 2023, the Committee for Veterinary Medicinal Products (CVMP) adopted a positive opinion², recommending the granting of a marketing authorisation for the veterinary medicinal product Eluracat 20 mg/ml oral solution for cats. The applicant for this veterinary medicinal product is Elanco GmbH.

Eluracat is a veterinary medicinal product containing capromorelin tartrate (ATCvet code) as active substance. Capromorelin tartrate is a selective ghrelin receptor agonist, which results in a stimulation of appetite and weight gain in cats.

The benefits of Eluracat are a body weight gain in cats with poor appetite or unintended weight loss resulting from chronic medical conditions. The most common side effects are hypersalivation at the time of dosing (resolved within a few minutes), diarrhoea, vomiting, anaemia, skin lesions (on the mouth and chin), dehydration and lethargy.

Detailed conditions for the use of this product are described in the summary of product characteristics (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, considers that there is a favourable benefit-risk balance for Eluracat and therefore recommends the granting of the marketing authorisation.

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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.