EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

19 July 2024
EMA/CVMP/313134/2024
Committee for Veterinary Medicinal Products

Summary of opinion[1] (initial authorisation)

Cepeloron

International non-proprietary name (INN): Spironolactone

On 18 July 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 Cepeloron chewable tablets for dogs. The applicant for this veterinary medicinal product is Cp-Pharma Handelsgesellschaft mbH.

Cepeloron contains spironolactone (QC03DA01) as active substance, an aldosterone antagonist, natriuretic substance, which inhibits the aldosterone-induced sodium retention leading to an increase in sodium and subsequently water excretion and potassium retention.

Cepeloron is a generic of Prilactone Next 10 mg chewable tablets for dogs, which has been authorised in the EU since 15 June 2012. Studies have demonstrated the satisfactory quality of Cepeloron, and its bioequivalence to the reference product.

The full indication is: Treatment of congestive heart failure caused by degenerative mitral valve disease, in combination with standard therapy (including diuretic support, where necessary) in dogs.

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 Cepeloron and therefore recommends the granting of the marketing authorisation.

[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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