11 September 2015
EMA/CVMP/478464/2015
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

Zycortal

International non-proprietary name (INN): desoxycortone

On 10 September 2015, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion[2], recommending the granting of a marketing authorisation for the veterinary medicinal product Zycortal 25 mg/ml prolonged-release suspension for injection, intended for use as replacement therapy for mineralocorticoid deficiency in dogs with established primary hypoadrenocorticism (Addison's disease). The applicant for this veterinary medicinal product is Dechra Limited.

The active substance of Zycortal is desoxycortone pivalate (ATCvet code QH02AA03), a corticosteroid with primarily mineralocorticoid activity. Administration of this veterinary medicinal product promotes water resorption from the kidneys, leading to an increase in blood volume and increased cardiovascular function.

The benefits of Zycortal are its efficacy in treating the mineralocorticoid deficiency in dogs with primary hypoadrenocorticism (Addison's disease). The most common side effects are excessive thirst and excessive urination.

Detailed conditions for the use of this product will be described in the summary of product characteristics (SPC) which will be published in the European Public Assessment Report (EPAR) 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 to risk balance for Zycortal and therefore recommends the granting of the marketing authorisation.

[1] Summaries of opinion are published without prejudice to the Commission Decision, which will normally be issued 90 days from adoption of the opinion.
[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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