17 June 2022
EMA/CVMP/579025/2022
Committee for Veterinary Medicinal Products

Summary of opinion[1] (initial authorisation)

Cortaderm

International non-proprietary name (INN): hydrocortisone aceponate

On 15 June 2022, the Committee for Veterinary Medicinal Products adopted a positive opinion[2], recommending the granting of a marketing authorisation for the veterinary medicinal product Cortaderm, a cutaneous spray solution, intended for dogs. The applicant for this veterinary medicinal product is Alfasan Nederland B.V.

Cortaderm is a dermatological medicinal product containing hydrocortisone aceponate (ATCvet code QD07AC) as active substance, with a potent intrinsic glucocorticoid activity. It accumulates in the dog's skin allowing high local activity with reduced systemic secondary effects.

The full indication is: for symptomatic treatment of inflammatory and pruritic dermatoses in dogs. For alleviation of clinical signs associated with atopic dermatitis.

The most common side effects are transient local reactions at the application site (erythema and/or pruritus) which can occur in very rare cases.

Detailed conditions for the use of this product are 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-risk balance for Cortaderm 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 67 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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