



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

16 February 2024
EMA/CVMP/44401/2024
Committee for Veterinary Medicinal Products

Summary of opinion¹ (initial authorisation)

Alcort

International non-proprietary name (INN): hydrocortisone aceponate

On 13-14 February 2024, the Committee for Veterinary Medicinal Products (CVMP) adopted a positive opinion², recommending the granting of a marketing authorisation for the veterinary medicinal product Alcort, Cutaneous spray, solution, intended for dogs. The applicant for this veterinary medicinal product is Nextmune Italy S.r.l..

Alcort 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 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 Alcort 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.

