

22 June 2018
EMA/CVMP/357032/2018
Committee for Medicinal Products for Veterinary Use

Summary of opinion¹ (initial authorisation)

Cortacare

International non-proprietary name (INN): hydrocortisone aceponate

On 21 June 2018, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion², recommending the granting of a marketing authorisation for the veterinary medicinal product Cortacare, a cutaneous spray solution, intended for symptomatic treatment of inflammatory and pruritic dermatoses in dogs. The applicant for this veterinary medicinal product is Ecuphar.

Cortacare is a corticosteroid dermatological medicinal product containing hydrocortisone aceponate (ATCvet code QD07AC16) 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 benefits of Cortacare are the relief of both inflammation and pruritus leading to a quick improvement of skin lesions observed in case of inflammatory and pruritic dermatoses. 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 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-risk balance for Cortacare 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.