15 March 2024
EMA/CVMP/105714/2024
Committee for Veterinary Medicinal Products

Summary of opinion[1] (initial authorisation)

Trilorale

International non-proprietary name (INN): Trilostane

On 12-13 March 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 Trilorale, oral suspension for dogs. The applicant for this veterinary medicinal product is Axience. The applicant is registered as an SME pursuant to the definition set out in Commission Recommendation 2003/361/EC.

Trilorale is an anticorticosteroid medicinal product containing Trilostane (QH02CA01) as active substance, an antiadrenal substance which selectively and reversibly inhibits the enzyme system 3 beta hydroxysteroid isomerase, thus blocking the production of cortisol, corticosterone and aldosterone.

The full indication is: For the treatment of pituitary-dependent and adrenal-dependent hyperadrenocorticism (Cushing's disease and syndrome) in dogs.

The most common side effects with uncommon frequency, i.e. 1 to 10 animals / 1,000 animals treated, are lethargy, vomiting, diarrhoea and anorexia.

Trilorale is a hybrid of Vetoryl, which has been authorised in the Ireland since 1 October 2010. Studies have demonstrated the satisfactory quality of Trilorale, and its bioequivalence to the reference product Vetoryl.

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 Trilorale 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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