10 October 2024
EMA/CVMP/446917/2024
Committee for Veterinary Medicinal Products

Summary of opinion[1] (initial authorisation)

Duotic

International non-proprietary name (INN): Betamethasone acetate / Terbinafine

On 10 October 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 Duotic, Ear gel, intended for Dog. The applicant for this veterinary medicinal product is Dechra Regulatory B.V..

The active substances of Duotic are betamethasone acetate and terbinafine (QS02CA90). Betamethasone acetate is a steroid with anti-inflammatory action. Terbinafine is an antifungal substance with action against *Malassezia pachydermatis*.

The full indication is: For the treatment of otitis externa associated with *Malassezia pachydermatis*.

The most common side effects with uncommon frequency, i.e. 1 to 10 animals / 1,000 animals treated, are elevated liver enzymes.

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 Duotic 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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