6 June 2014
EMA/CVMP/290192/2014
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

Osurnia

International non-proprietary name (INN): Florfenicol, terbinafine, betamethasone acetate

On 5 June 2014, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion[2], recommending the granting of a marketing authorisation for the veterinary medicinal product Osurnia, an ear gel for dogs intended for the treatment of otitis externa. The applicant for this veterinary medicinal product is Novartis Santé Animale S.A.S.

The active substances of Osurnia are terbinafine, florfenicol and betamethasone acetate. Terbinafine is an antifungal substance with action against *Malassezia pachydermatis*, and a new substance in veterinary medicines. Florfenicol is an antibacterial substance with action against *Staphylococcus pseudintermedius.* Betamethasone acetate is a steroid with anti-inflammatory action.

The benefits of Osurnia are its efficacy for the treatment of otitis externa and acute exacerbation of recurrent otitis externa associated with *Staphylococcus pseudintermedius* and *Malassezia pachydermatis*. Osurnia is generally well tolerated at the recommended dose; a reversible decrease in serum cortisol level (indicating that betamethasone is absorbed and enters the systemic circulation) was not correlated with pathological or clinical signs.

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 to risk balance for Osurnia 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 within 90 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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