EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 October 2019
EMA/CVMP/513917/2019
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

Neptra

International non-proprietary name (INN): florfenicol / terbinafine hydrochloride / mometasone furoate

On 10 October 2019, 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 Neptra, ear drops, solution in single-dose container, intended for dogs. The applicant for this veterinary medicinal product is Bayer Animal Health GmbH.

Neptra is an anti-infective and corticosteroid medicinal product containing florfenicol / terbinafine hydrochloride / mometasone furoate (ATCvet code QS02CA91) as active substances. Florfenicol is a bacteriostatic antibiotic which acts by inhibiting protein synthesis and is active in gram positive and negative bacteria; terbinafine hydrochloride is an allylamine with pronounced fungicidal activity as it inhibits the early synthesis of ergosterol, an essential component of the membrane of yeasts and fungi; and mometasone furoate is a corticosteroid with anti-inflammatory and anti-pruritic properties.

The benefits of Neptra are its effectiveness in the treatment of acute otitis externa or acute exacerbations of recurrent otitis caused by mixed infections of susceptible strains of bacteria sensitive to florfenicol and fungi sensitive to terbinafine. Neptra is generally well tolerated with adverse reactions being only classified as very rare. These include vocalisation, head shaking and pain and/or inflammation at the application site shortly after product application.

The full indication is: For the treatment of canine otitis externa caused by susceptible strains of bacteria sensitive to florfenicol (*Staphylococcus pseudintermedius*) and fungi sensitive to terbinafine (Malassezia pachydermatis).

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.

[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.

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The CVMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit-risk balance for Neptra and therefore recommends the granting of the marketing authorisation.