7 October 2022
EMA/CVMP/793345/2022
Committee for Veterinary Medicinal Products

Summary of opinion[1] (initial authorisation)

Mometamax Ultra

International non-proprietary name (INN): gentamicin / posaconazole / mometasone furoate

On 6 October 2022, the Committee for Veterinary Medicinal Products (CVMP) adopted a positive opinion[2] recommending the granting of a marketing authorisation for the veterinary medicinal product Mometamax Ultra, ear drops, suspension, intended for dogs. The applicant for this veterinary medicinal product is Intervet International B.V.

Mometamax Ultra is an anti-infective and corticosteroid medicinal product containing gentamicin, posaconazole and mometasone furoate (ATCvet code QS02CA91) as active substances.

Gentamicin is an aminoglycoside bactericidal antibiotic which acts by inhibiting protein synthesis, posaconazole is a broad-spectrum triazole antifungal agent, whilst mometasone furoate is a corticosteroid with high topical potency.

The benefits of Mometamax Ultra are its effectiveness in the treatment of acute otitis externa or acute exacerbations of recurrent otitis caused by mixed infections of bacteria susceptible to gentamicin (*Staphylococcus pseudintermedius*) and fungi susceptible to posaconazole (*Malassezia pachydermatis*). Mometamax Ultra is generally well tolerated at the recommended dose, adverse reactions, consistent with glucocorticoid administration were only seen at overdoses.

Detailed conditions for the use of this product are 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 Mometamax Ultra 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.

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