14 February 2025
EMA/CVMP/28067/2025
Committee for Veterinary Medicinal Products

Summary of opinion[1] (initial authorisation)

Vectormune HVT-AIV

Common name: Avian influenza vaccine (live, recombinant)

On 12 February 2025, the Committee for Veterinary Medicinal Products (CVMP) adopted a positive opinion[2], recommending the granting of a marketing authorisation for the veterinary medicinal product Vectormune HVT-AIV, concentrate and solvent for suspension for injection, intended for one day-old chicken. The applicant for this veterinary medicinal product is CEVA Sante Animale.

Vectormune HVT-AIV is a cell-associated, live recombinant vector vaccine containing one active substance: the recombinant live turkey herpes virus (HVT, Marek's disease serotype 3) genetically modified to express the haemagglutinin 5 (H5) encoding the gene of highly pathogenic avian influenza virus (HPAIV) H5N1.

The benefits of Vectormune HVT-AIV is the active immunisation of one-day-old chicks to reduce mortality, clinical signs and virus excretion due to infection with highly pathogenic avian influenza (HPAI) virus of the H5 sub-type. The onset of immunity is 2 weeks and the duration of immunity is 19 weeks.

Vectormune HVT-AIV is generally well tolerated at the recommended dose.

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 Vectormune HVT-AIV and therefore recommends the granting of the marketing authorisation in exceptional circumstances[3].

[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.
[3] Marketing authorisation under exceptional circumstances refers to the fact that in exceptional circumstances an authorisation may be granted subject to certain specific obligations, to be reviewed annually.

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