21 February 2020
EMA/CVMP/62052/2020
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

Vectormune FP ILT + AE

Common name: fowlpox, avian infectious laryngotracheitis vaccine (live, recombinant) and avian encephalomyelitis vaccine (live)

On 20 February 2020, 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 Vectormune FP ILT + AE, lyophilisate and solvent for suspension for injection for chickens.

The applicant for this veterinary medicinal product is Ceva-Phylaxia Co. Ltd.

Vectormune FP ILT + AE is an immunological veterinary medicinal product containing live recombinant fowlpox virus (FPV) expressing the membrane fusion protein and the encapsidation protein of avian infectious laryngotracheitis virus (ILTV), and live avian encephalomyelitis virus (AEV), strain Calnek, as active substances.

The benefit of Vectormune FP ILT + AE is the stimulation of active immunity in layer pullets from 8 weeks of age in order to reduce skin lesions caused by FPV, to reduce clinical signs and tracheal lesions due to ILTV and to prevent a drop in egg production caused by AEV.

The onset of immunity is 3 weeks after vaccination for FPV and ILTV, and 20 weeks after vaccination for AEV. The duration of immunity is 57 weeks post vaccination for ILTV and AEV and 34 weeks for FPV.

Vectormune FP ILT + AE combines protection against three important poultry diseases, limiting the number of times the animals are required to be handled; it reduces the need for live attenuated ILTV vaccination and thus may help reduce the occurrence of new virulent strains due to recombination in the field; and it was shown to be apathogenic to other avian species, limiting the risk to the environment.

Vectormune FP ILT + AE is generally well tolerated at the recommended dose and no adverse reactions were observed after an overdose.

[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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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-risk balance for Vectormune FP ILT + AE and therefore recommends the granting of the marketing authorisation.