

9 October 2020 EMA/CVMP/505185/2020 Committee for Medicinal Products for Veterinary Use

Summary of opinion¹ (initial authorisation)

Vectormune FP ILT

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

On 7 October 2020, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion², recommending the granting of a marketing authorisation for the veterinary medicinal product Vectormune FP ILT, lyophilisate and solvent for suspension for injection, intended for chickens. The applicant for this veterinary medicinal product is Ceva-Phylaxia Co. Ltd.

Vectormune FP ILT is an immunological veterinary medicinal product containing live recombinant fowlpox virus expressing the membrane fusion protein and the encapsidation protein of avian infectious laryngotracheitis virus (ATCvet code not yet assigned) as active substance, which induces active immunity against fowlpox virus (FPV) and avian infectious laryngotracheitis virus (ILTV).

The benefits of Vectormune FP ILT are its active immunisation of layer pullets from 8 weeks of age, where the immunity against FP and ILT infection starts at 3 weeks after vaccination and lasts for 34 weeks post vaccination for FPV and 57 weeks post vaccination for ILTV. Vectormune FP ILT combines protection against two important poultry diseases, which limits the number of times the animals are required to be handled. Vectormune FP ILT 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. The very common side effects are small swelling/scabs at the application site, which should disappear within 14 days after vaccination.

The full indication is: For active immunisation of chickens from 8 weeks of age in order to reduce the skin lesions due to fowlpox and to reduce the clinical signs and tracheal lesions due to avian infectious laryngotracheitis. Onset of immunity: fowlpox and avian infectious laryngotracheitis: 3 weeks after vaccination. Duration of immunity: fowlpox: 34 weeks after vaccination; avian infectious laryngotracheitis: 57 weeks after vaccination.

Detailed conditions for the use of this product are described in the summary of product characteristics



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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.

(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 and therefore recommends the granting of the marketing authorisation.