6 December 2024
EMA/CVMP/442900/2024
Committee for Veterinary Medicinal Products

Summary of opinion[1] (initial authorisation)

Poulvac Procerta HVT-IBD-ND

Common name: Marek's disease, infectious bursal disease and Newcastle disease vaccine (live recombinant)

On 5 December 2024, the Committee for Veterinary Medicinal Products (CVMP) adopted a positive opinion[2], recommending the granting of a marketing authorisation for the veterinary medicinal product Poulvac Procerta HVT-IBD-ND, Concentrate and solvent for suspension for injection, intended for chickens and embryonated chicken eggs. The applicant for this veterinary medicinal product is Zoetis Belgium.

Poulvac Procerta HVT-IBD-ND is a vaccine containing Turkey herpesvirus, strain HVT-IBD-ND (cell-associated), expressing VP2 protein gene of infectious bursal disease virus and fusion protein gene of Newcastle disease virus, live (ATCvet code QI01AD16) as active substance. The vaccine induces active immunity against MD, IBD (Gumboro disease) and ND in chickens.

The benefits of Poulvac Procerta HVT-IBD-ND are its efficacy in providing the active immunisation of one day old chickens and 18-19 day old embryonated chicken eggs to reduce mortality, clinical signs and lesions caused by Marek's disease (MD) virus and infectious bursal disease (IBD) virus and reduce mortality and clinical signs caused by Newcastle disease (ND) virus.

Poulvac Procerta HVT-IBD-ND is generally well tolerated at the recommended dose.

Poulvac Procerta HVT-IBD-ND is indicated for the active immunisation of one day old chickens and 18-19 day old embryonated chicken eggs to

- reduce mortality, clinical signs and lesions caused by Marek's disease (MD) virus;
- reduce mortality, clinical signs and lesions caused by infectious bursal disease (IBD) virus and
- reduce mortality and clinical signs caused by Newcastle disease (ND) virus.

[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.

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Onset of immunity: MD: 9 days post vaccination for in ovo and subcutaneous use

IBD: 21 days post vaccination for in ovo and 14 days for subcutaneous use

ND: 24 days post vaccination for in ovo and 21 days for subcutaneous use

Duration of immunity: MD: a single vaccination is sufficient to provide protection for the entire risk period

IBD: 63 days of age

ND: 63 days of age

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 Poulvac Procerta HVT-IBD-ND and therefore recommends the granting of the marketing authorisation.