9 October 2020
EMA/CVMP/507630/2020
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (post-authorisation)

Innovax-ND-IBD

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

On 7 October 2020, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion[2], recommending the granting of a variation to the terms of the marketing authorisation for the veterinary medicinal product Innovax-ND-IBD. The marketing authorisation holder for this veterinary medicinal product is Intervet International B.V.

Innovax-ND-IBD is currently authorised as concentrate and solvent for suspension for injection. The variation concerns the extension of the duration of immunity for the protection against Newcastle disease (ND) and infectious bursal disease (IBD) from 8 weeks to 60 weeks.

Detailed conditions for the use of this product are described in the updated summary of product characteristics (SPC), for which an updated version reflecting the changes will be published in the revised European public assessment report (EPAR) and will be available in all official European Union languages after the variation to the marketing authorisation has been granted by the European Commission.

[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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