25 April 2024
EMA/CVMP/165069/2024
Committee for Veterinary Medicinal Products

Summary of opinion[1] (initial authorisation)

Innovax-ND-H5

Common name: Newcastle disease, avian influenza and Marek's disease vaccine (live recombinant)

On 18 April 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 Innovax-ND-H5, concentrate and solvent for suspension for injection, intended for chickens. The applicant for this veterinary medicinal product is Intervet International B.V.

Innovax-ND-H5 is an immunological medicinal product containing turkey herpesvirus, strain HVT-ND-H5 (cell-associated), expressing fusion protein gene of Newcastle disease virus and haemagglutinin gene of avian influenza virus subtype H5 (ATCvet code QI01AD) as active substance.

The benefit of Innovax-ND-H5 is the active immunisation of one-day-old chicks or 18–19 day-old embryonated chicken eggs to reduce mortality, clinical signs and virus excretion due to infection with highly pathogenic Avian Influenza (HPAI) virus of the H5 type. The onset of immunity is 2 weeks and the duration of immunity is 12 weeks (reduction of mortality and clinical signs demonstrated with *in ovo* administration).

Innovax-ND-H5 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 Innovax-ND-H5 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 in exceptional circumstances refers to the fact that in exceptional circumstances an authorisation may be granted subject to requirements or conditions, to be fulfilled by the marketing authorisation holder.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union