11 April 2025
EMA/CVMP/98876/2025
Committee for Veterinary Medicinal Products

Summary of opinion[1] (initial authorisation)

Nobilis Multriva IBm+ND

Common name: Avian infectious bronchitis virus and Newcastle disease virus vaccine (inactivated)

On 9 April 2025, the Committee for Veterinary Medicinal Products (CVMP) adopted a positive opinion[2], recommending the granting of a marketing authorisation for the veterinary medicinal product Nobilis Multriva IBm+ND, emulsion for injection, intended for chickens. The applicant for this veterinary medicinal product is Intervet International B.V.

Nobilis Multriva IBm+ND is an immunological veterinary medicinal product containing inactivated avian infectious bronchitis virus, type Massachusetts, strain M41, inactivated avian infectious bronchitis virus (IBV), type 793/B, strain 4-91 and inactivated Newcastle disease virus (NDV), strain Ulster (ATCvet code QI01AA10) as active substances. The vaccine is intended to stimulate active immunity against infectious bronchitis virus and Newcastle disease virus.

The benefit of Nobilis Multriva IBm+ND is its efficacy on the active immunisation of chickens for the reduction of respiratory signs and egg drop caused by infectious bronchitis virus strains Massachusetts (GI-1 genotype) and 4/91-793B (GI-13 genotype) and reduction of mortality and clinical signs caused by Newcastle disease virus.

A side effect uncommonly observed is injection site lump.

The full indication is: For the active immunisation of chickens for:
- reduction of respiratory signs and egg drop caused by infectious bronchitis virus strains Massachusetts (GI-1 genotype) and 4/91-793B (GI-13 genotype);
- reduction of mortality and clinical signs caused by Newcastle disease virus.

Onset of immunity: 4 weeks post-vaccination.

Duration of immunity: 80 weeks post-vaccination.

[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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Cross-protection has been established for IBV strains QX-D388 (GI-19 genotype), Var2 (GI-23 genotype) and Q1 (GI-16 genotype).

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 Nobilis Multriva IBm+ND and therefore recommends the granting of the marketing authorisation.