



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

14 March 2025
EMA/CVMP/74106/2025
Committee for Veterinary Medicinal Products

Summary of opinion¹ (initial authorisation)

Nobilis Multiriva IBm+ND+EDS

Common name: Infectious Bronchitis, Newcastle disease and Egg Drop Syndrome virus vaccine (inactivated)

On 13 March 2025, the Committee for Veterinary Medicinal Products (CVMP) adopted a positive opinion², recommending the granting of a marketing authorisation for the veterinary medicinal product Nobilis Multiriva IBm+ND+EDS, emulsion for injection, intended for chickens. The applicant for this veterinary medicinal product is Intervet International B.V.

Nobilis Multiriva IBm+ND+EDS is an immunological veterinary medicinal product containing inactivated avian infectious bronchitis virus, type Massachusetts, strain M41, inactivated avian infectious bronchitis virus, type 793/B, strain 4-91, inactivated Newcastle disease virus, strain Ulster and inactivated egg drop syndrome-1976 virus, strain BC14 (ATCvet code QI01AA13) as active substances. The vaccine is intended to stimulate active immunity against infectious bronchitis virus, Newcastle disease virus and eggdrop syndrome-1976 virus.

The benefit of Nobilis Multiriva IBm+ND+EDS is its efficacy on the active immunisation of chickens for the reduction of respiratory signs and egg drop caused by infectious bronchitis virus (IBV) strains Massachusetts (GI-1 genotype) and 4/91-793B (GI-13 genotype), reduction of mortality and clinical signs caused by Newcastle disease virus (NDV) and reduction of egg drop and eggshell defects caused by egg drop syndrome-1976 virus (EDSV).

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.
- reduction of egg drop and eggshell defects caused by egg drop syndrome-1976 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.



Onset of immunity: 4 weeks post-vaccination.

Duration of immunity: 80 weeks post-vaccination

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 Multiriva IBm+ND+EDS and therefore recommends the granting of the marketing authorisation.