24 May 2024
EMA/CVMP/189378/2024
Committee for Veterinary Medicinal Products

Summary of opinion[1] (initial authorisation)

Nobilis Multriva RT+IBm+ND+EDS

Common name: Avian metapneumovirus, infectious bronchitis virus, Newcastle disease virus and eggdrop syndrome virus vaccine (inactivated)

On 22 May 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 Nobilis Multriva RT+IBm+ND+EDS emulsion for injection, intended for chickens. The applicant for this veterinary medicinal product is Intervet International B.V.

Nobilis Multriva RT+IBm+ND+EDS is an immunological veterinary medicinal product containing avian metapneumovirus, strain BUT1 #8544, inactivated; infectious bronchitis virus, type Massachusetts, strain M41, inactivated; avian infectious bronchitis virus, type 793/B, strain 4-91, inactivated; Newcastle disease virus, strain Ulster, inactivated; and eggdrop syndrome-1976 virus, strain BC14, inactivated, as active substances. These active substances act by stimulating active immunity against avian rhinotracheitis virus, infectious bronchitis virus, Newcastle disease virus, and eggdrop syndrome virus.

The benefits of Nobilis Multriva RT+IBm+ND+EDS are its efficacy against AMPV, IBV, NDV and EDSV, reducing the need for the application (injection) of different vaccines within a short timeframe. Compared to existing inactivated viral vaccine combinations, the dose volume is smaller which is an advantage with respect to injection-site safety and animal welfare.

The most common side effects are injection site lumps, which generally disappear within 3 weeks.

The full indication is:

"For the active immunisation of chickens for:
- reduction of egg drop caused by avian metapneumovirus (AMPV).
- 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 (NDV).

[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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- reduction of egg drop and eggshell defects caused by eggdrop syndrome-1976 virus (EDSV).

Onset of immunity:
- IBV, NDV, and EDSV: 4 weeks post-vaccination
- AMPV: 5 weeks post-vaccination

Duration of immunity:
- AMPV, IBV, NDV, and EDSV: 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 Multriva RT+IBm+ND+EDS and therefore recommends the granting of the marketing authorisation.