EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 May 2024
EMA/CVMP/187085/2024
Committee for Veterinary Medicinal Products

Summary of opinion[1] (initial authorisation)

Nobilis Multriva RT+IBm+ND+Gm+REOm

Common name: Avian metapneumovirus, avian infectious bronchitis virus, Newcastle disease virus, avian infectious bursal disease virus and avian reovirus 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+Gm+REOm emulsion for injection, intended for chickens. The applicant for this veterinary medicinal product is Intervet International B.V.

Nobilis Multriva RT+IBm+ND+Gm+REOm is an immunological veterinary medicinal product containing avian metapneumovirus, strain BUT1 #8544, inactivated; infectious bronchitis virus, type Massachusetts, strain M41, inactivated; infectious bronchitis virus, type 793/B, strain 4-91, inactivated; Newcastle disease virus, strain Ulster, inactivated; infectious bursal disease virus, strain GB02, inactivated; infectious bursal disease virus, strain 89/03, inactivated; avian reovirus, strain ARV-1, inactivated; and avian reovirus, strain ARV-4, inactivated as active substances. These active substances act by stimulating active immunity against avian rhinotracheitis virus, infectious bronchitis virus and Newcastle disease virus, and to stimulate active immunity in order to provide passive immunity to the progeny against infectious bursal (Gumboro) disease virus and avian reovirus.

The benefits of Nobilis Multriva RT+IBm+ND+Gm+REOm are its efficacy against AMPV, IBV, NDV, IBDV, and ARV, 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:

[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 caused by avian metapneumovirus (AMPV)
- 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)
- passive immunisation of the progeny of the vaccinated chickens to:
- reduce mortality and clinical signs of disease caused by very virulent (CS89) and classical (STC) infectious bursal disease virus (IBDV).
- reduce viraemia and clinical signs of disease caused by avian reovirus (genotypes 1 and 4).
Onset of immunity:
- IBV, NDV, IBDV and ARV: 4 weeks post-vaccination
- AMPV: 5 weeks post-vaccination
- IBDV and ARV in progeny: 1 day of age
Duration of immunity:
- AMPV, IBV, NDV, IBDV and ARV: 80 weeks post-vaccination
- IBDV and ARV in progeny: 3 weeks of age"

Cross protection has been established for IBV strains QX-D388 (GI-19 genotype), Var2 (GI-23 genotype) and Q1 (GI-16 genotype).
Cross protection has been established for IBDV antigenic variant strains (variant E and GLS).
Cross protection has been established for ARV genotypes 2, 3 and 5.

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+Gm+REOm and therefore recommends the granting of the marketing authorisation.