15 March 2024
EMA/CVMP/90386/2024
Committee for Veterinary Medicinal Products

Summary of opinion[1] (initial authorisation)

Nobilis Multriva RT+IBm+ND+Gm+REOm+EDS

Common name: Avian metapneumovirus, avian infectious bronchitis, Newcastle disease, avian infectious bursal disease, avian reovirus and egg drop syndrome virus vaccine (inactivated)

On 12-13 March 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+EDS, emulsion for injection, intended for chicken. The applicant for this veterinary medicinal product is Intervet International B.V..

Nobilis Multriva RT+IBm+ND+Gm+REOm+EDS is an immunological veterinary medicinal product containing inactivated avian metapneumovirus strain BUT1 #8544, inactivated avian infectious bronchitis strain M41, inactivated avian infectious bronchitis strain 4/91, inactivated Newcastle disease virus strain Ulster, inactivated avian infectious bursal disease virus strain GB02, inactivated avian infectious bursal disease virus strain 89/03, inactivated avian reovirus strain ARV-1, inactivated avian reovirus strain ARV-4 and inactivated egg drop syndrome '76 virus strain BC14, as active substances (ATCvet code QI01AA24).

The benefits of Nobilis Multriva RT+IBm+ND+Gm+REOm+EDS are 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 (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 the 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) strains of infectious bursal disease virus (IBDV), reduce viraemia and clinical signs of disease caused by avian reovirus (ARV) genotypes 1 and 4; and reduction of egg drop and eggshell defects caused by egg drop syndrome 1976 virus (EDSV).

[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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The onset of immunity is 4 weeks post-vaccination for IBV, NDV, IBDV, ARV and EDSV; 5 weeks post-vaccination for AMPV and one day of age for IBDV and ARV (in progeny). The duration of immunity is 80 weeks for AMPV, IBV, NDV, IBDV, ARV and EDSV and 3 weeks of age for IBDV and ARV (in progeny).

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.

Nobilis Multriva RT+IBm+ND+Gm+REOm+EDS is generally well tolerated at the recommended dose. The most common side effects are injection site lumps after vaccination which generally disappear within 3 weeks.

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+EDS and therefore recommends the granting of the marketing authorisation.