EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 April 2025
EMA/CVMP/113812/2025
Committee for Veterinary Medicinal Products

Summary of opinion[1] (initial authorisation)

Nobilis Multriva Gm+REOm

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

Nobilis Multriva Gm+REOm is an immunological veterinary medicinal product containing inactivated infectious bursal disease virus, strain GB02, inactivated infectious bursal disease virus, strain 89/03, inactivated avian reovirus, strain ARV-1 and inactivated avian reovirus, strain ARV-4 (ATCvet code QI01AA13) as active substances. The vaccine is intended to stimulate active immunity against infectious bursal disease virus and avian reovirus.

The benefits of Nobilis Multriva Gm+REOm is the active immunisation of chickens for 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), and to reduce viraemia and clinical signs of disease caused by avian reovirus (ARV) genotypes 1 and 4.

Onset of immunity:
- 4 weeks post-vaccination
- In progeny: 1 day of age

Duration of immunity:
- 80 weeks post-vaccination
- In progeny: 3 weeks of age

[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 IBDV antigenic variant strains (variant E and GLS).

Cross protection has been established for ARV genotypes 2, 3 and 5.

The most common side effects are injection site lumps which occur uncommonly and disappear within 3 weeks after vaccination.

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