EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 October 2024
EMA/CVMP/446894/2024
Committee for Veterinary Medicinal Products

Summary of opinion[1] (initial authorisation)

VAXXON ND CLONE

Common name: Newcastle disease vaccine live

On 10 October 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 VAXXON ND CLONE, lyophilisate and solvent for oculonasal suspension; lyophilisate for oculonasal suspension, intended for chickens. The applicant for this veterinary medicinal product is Vaxxinova International B.V..

VAXXON ND CLONE is an immunological veterinary medicinal product containing Newcastle disease virus, strain Clone, live attenuated (ATCvet code: QI01AD06) as active substance. The product stimulates active immunity of chicken from one day of age against Newcastle disease virus.

The benefit of VAXXON ND CLONE is the reduction of mortality and clinical signs of disease caused by infection with Newcastle disease virus.

The most common side effects are cough, decreased activity and head shake.

The full indication is: For the active immunisation of chickens (broilers, future layers and breeders) from one day of age to reduce mortality and clinical signs of disease caused by infection with Newcastle disease virus.
Onset of immunity: 3 weeks after vaccination
Duration of immunity: 8 weeks (broilers) and 10 weeks (future layers and breeders)

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 VAXXON ND CLONE and therefore recommends the granting of the marketing authorisation.

[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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