7 November 2025
EMA/CVMP/341546/2025
Committee for Veterinary Medicinal Products

Summary of opinion[1] (initial authorisation)

Vaxxinact H5

Common name: Avian influenza vaccine (subunit recombinant)

On 6 November 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 Vaxxinact H5, Emulsion for injection, intended for chicken, duck and turkey. The applicant for this veterinary medicinal product is Boehringer Ingelheim Vetmedica GmbH.

Vaxxinact H5 is an immunological medicinal product containing 'Avian influenza virus, subtype H5, haemagglutinin (recombinant)' (ATCvet code QI01AA23) as the active substance. The vaccine induces an active immunity against avian influenza in chickens, turkeys and ducks (pekin, muscovy, and Mulard).

The benefits of Vaxxinact H5 are:

Chickens:
Active immunisation of chickens from 10 days of age to prevent mortality, clinical signs and reduce viral excretion associated with highly pathogenic avian influenza (HPAI) infection related to H5, including the circulating clade 2.3.4.4b.

For use in chickens either as a single dose from 10 days of age (for example, in broilers) or as a booster vaccine in a prime-boost vaccination scheme (for example, in layers and breeders). See section 3.9 of the summary of product characteristics.

Onset of immunity: 21 days after vaccination.
Duration of immunity: 6 weeks after vaccination (without priming with a vHVT-H5 vaccine) or 12 weeks after vaccination (with priming with a vHVT-H5 vaccine).

Ducks:
Mulard

Active immunisation of Mulard ducks from 1 day of age or older to prevent mortality, clinical signs and

[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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reduce viral excretion associated with HPAI infection related to H5, including the circulating clade 2.3.4.4b.

Onset of immunity: 14 days after the vaccination.

Duration of immunity: 9 weeks after vaccination.

Pekin

Active immunisation of Pekin ducks from 1 day of age or older to reduce viral excretion associated with HPAI infection related to H5, including the circulating clade 2.3.4.4b.

Onset of immunity: 21 days after the vaccination.

Duration of immunity: 7 weeks after vaccination.

Muscovy

Active immunisation of Muscovy ducks from 1 day of age or older to reduce mortality, clinical signs and viral excretion associated with HPAI infection related to H5, including the circulating clade 2.3.4.4b.

Onset of immunity: 21 days after the vaccination.

Duration of immunity: 7 weeks after vaccination.

Turkeys:
Active immunisation of turkeys from 28 days of age, after priming with a vHVT-H5 vaccine, to reduce mortality, clinical signs and viral excretion associated with HPAI infection related to H5, including the circulating clade 2.3.4.4b.

Onset of immunity: 21 days after vaccination.
Duration of immunity: 9 weeks after vaccination.

The most common side effects are injection site reactions in chickens; injection site swelling, injection site reddening and injection site crust in ducks; injection site swelling, injection site reddening, injection site mass and injection site thickening in turkeys.

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 Vaxxinact H5 and therefore recommends the granting of the marketing authorisation under exceptional circumstances[3].

[3] Marketing authorisation under exceptional circumstances refers to the fact that in exceptional circumstances an authorisation may be granted subject to certain specific obligations, to be reviewed annually.