



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

10 October 2025
EMA/CVMP/307532/2025
Committee for Veterinary Medicinal Products

Summary of opinion¹ (initial authorisation)

Vaxxitek HVT+IBD+H5

Common name: Avian influenza vaccine (live recombinant)

On 9 October 2025, the Committee for Veterinary Medicinal Products (CVMP) adopted a positive opinion², recommending the granting of a marketing authorisation for the veterinary medicinal product Vaxxitek HVT+IBD+H5, concentrate and solvent for suspension for injection, intended for chickens, turkeys and embryonated chicken eggs. The applicant for this veterinary medicinal product is Boehringer Ingelheim Vetmedica GmbH.

Vaxxitek HVT+IBD+H5 is an immunological veterinary medicinal product containing 'Turkey herpesvirus, strain rHVT-IBD-H5 (cell-associated), expressing the VP2 protein gene of Infectious bursal disease virus and haemagglutinin gene of Avian influenza virus subtype H5, live' (ATCvet code QI01AD) as the active substance. The vaccine induces an active immunity and a serological response against avian influenza in chickens and turkeys.

The benefit of Vaxxitek HVT+IBD+H5 is:

- chickens and embryonated chicken eggs: the active immunisation of one-day-old chicks or 18-day-old embryonated chicken eggs to reduce mortality, clinical signs and virus excretion due to infection with highly pathogenic avian influenza virus (HPAI) virus of the H5 subtype, including the circulating clade 2.3.4.4b.
- turkeys: the active immunisation of one-day-old turkeys to reduce mortality, clinical signs and virus excretion due to infection with HPAI virus of the H5 subtype, including the circulating clade 2.3.4.4b

Vaxxitek HVT+IBD+H5 is generally well tolerated at the recommended dose.

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.



The full indication is:

Chickens and embryonated chicken eggs:

For active immunisation of one-day-old chicks or 18-day-old embryonated chicken eggs:

To reduce mortality, clinical signs and virus excretion due to infection with highly pathogenic avian influenza virus (HPAI) virus of the H5 subtype, including the circulating clade 2.3.4.4b.

Onset of immunity: 4 weeks

Duration of immunity: 24 weeks

Turkeys:

For active immunisation of one-day-old turkeys:

To reduce mortality, clinical signs and virus excretion due to infection with HPAI virus of the H5 subtype, including the circulating clade 2.3.4.4b.

Onset of immunity: 50 days

Duration of immunity: 100 days

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 Vaxxitek HVT+IBD+H5 and therefore recommends the granting of the marketing authorisation under exceptional circumstances³.

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.