**ANNEX I**

**SUMMARY OF PRODUCT CHARACTERISTICS**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vaxxitek HVT+IBD+H5 concentrate and solvent for suspension for injection

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of the reconstituted vaccine (0.2 ml for subcutaneous use or 0.05 ml for *in ovo* use) contains:

**Active substance:**
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: ≥ 3.6 to 4.4 $\log_{10}$ PFU*

*PFU: plaque forming unit.

**Excipients:**

| **Qualitative composition of excipients and other constituents** |
|---|
| **Concentrate:** |
| Dimethyl sulfoxide |
| 199 Earle medium |
| Sodium hydrogen carbonate |
| Hydrochloric acid |
| Water for injections |
| **Solvent:** |
| Sucrose |
| Casein hydrolysate |
| Phenol red 1 % solution |
| Salts |
| Water for injections |

Concentrate: yellow to reddish pink opalescent homogeneous suspension.
Solvent: red-orange limpid solution.

## 3. CLINICAL INFORMATION

### 3.1 Target species

Chickens, turkeys and embryonated chicken eggs.

### 3.2 Indications for use for each target species

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

### 3.3 Contraindications

None.

### 3.4 Special warnings

Vaccinate healthy animals only.

HVT maternally derived antibodies had no effect on HPAI H5 protection when the vaccine was administered by the subcutaneous route to one-day-old chicks and turkeys. It was not investigated with the *in ovo* route.
The effect of HPAI H5 maternally derived antibodies on the effect on HPAI H5 protection in chickens and turkeys has not yet been investigated.

### 3.5 Special precautions for use

Special precautions for safe use in the target species:
Apply the usual aseptic precautions to all administration procedures.

As a live vaccine, the vaccine strain is excreted from vaccinated chickens and turkeys and may spread to contact turkeys. Safety trials have shown that the strain is safe for turkeys. However, precautionary measures have to be followed in order to avoid direct or indirect contact between vaccinated chickens and turkeys.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Personal protective equipment consisting of gloves, spectacles and boots should be worn when handling the veterinary medicinal product, before withdrawing from liquid nitrogen, and during both the ampoule thawing and opening operations. Frozen glass ampoules may explode during sudden temperature changes. Store and use liquid nitrogen only in a dry and well-ventilated place. Inhalation of the liquid nitrogen is dangerous.

Special precautions for the protection of the environment:
Not applicable.

### 3.6 Adverse events

Chickens and turkeys:

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

### 3.7 Use during pregnancy, lactation or lay

This veterinary medicinal product is designed for one-day-old birds and 18-day-old embryonated chicken eggs therefore the safety of the veterinary medicinal product has not been established during lay.

### 3.8 Interaction with other medicinal products and other forms of interaction

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product. A decision to use this vaccine before or after any other veterinary medicinal product therefore needs to be made on a case-by-case basis.

### 3.9 Administration routes and dosage

Subcutaneous or *in ovo* route.

Reconstitution of the vaccine:

- Wear protective gloves, spectacles and boots during the ampoule thawing and opening operations. The handling of liquid nitrogen should take place in a well-ventilated area.
- Remove from the liquid nitrogen container only those ampoules which are to be used immediately.
- Thaw the contents of the ampoules rapidly by agitation in water at 25 °C - 30 °C. Proceed immediately to next step.
- As soon as they are thawed, open ampoules holding them at arm's length in order to prevent any risk of injury if any ampoule breaks.
- Select an appropriately sized sterile syringe to withdraw the vaccine from all the ampoules that are thawed and fit it with a needle of 18 gauge or larger.
- Gently insert the syringe needle through the septum of one of the bag's connecting tubes and withdraw 2 ml of solvent.
- Then draw up the complete contents of all the thawed ampoules into the syringe.
- Transfer the syringe contents into the solvent bag (do not use the solvent if it is cloudy).
- Gently mix the vaccine in the solvent bag by moving the bag back and forth.
- It is important to rinse the ampoules and ampoule tips. To do this, draw up a small volume of the solvent containing the vaccine into the syringe. Then slowly fill the ampoule bodies and tips with it. Withdraw the content from the ampoule bodies and tips and inject it back into the solvent bag.
- Repeat the thawing, opening, transfer and rinsing operations for the appropriate number of ampoules to be reconstituted in the solvent; either 1 ampoule of 2 000 doses of vaccine per 400 ml of solvent for subcutaneous administration, or 4 ampoules of 2 000 doses of vaccine per 400 ml of solvent for *in ovo* administration.
- The vaccine is a clear, red-orange coloured suspension ready for use. It should be mixed by gentle agitation and used immediately and up to two hours. During vaccination, gently swirl the bag frequently to ensure the vaccine remains homogenously mixed. Do not freeze it under any circumstances. Do not re-use opened containers of vaccine.

Posology and method of administration:
One single injection of 0.2 ml per chicken or turkey at the age of one day, by subcutaneous route.
One single injection of 0.05 ml per chicken egg at 18 days of embryonation, by *in ovo* route.

For *in ovo* administration, an automated egg injection machine can be used. The device should be proven to safely and effectively deliver the appropriate dose. The instructions for use of this device should be strictly followed.

### 3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

None known.

### 3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Any person intending to manufacture, import, possess, distribute, sell, supply and use this veterinary medicinal product must first consult the relevant Member State's competent authority on the current vaccination policies, as these activities may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation.

### 3.12 Withdrawal periods

Zero days.

## 4. IMMUNOLOGICAL INFORMATION

### 4.1 ATCvet code: QI01AD

The vaccine strain is a recombinant herpesvirus of turkeys (HVT) expressing the protective antigen gene (VP2) of the infectious bursal disease virus (IBDV) strain Faragher 52/70 and a consensus haemagglutinin antigen gene of the avian influenza virus H5 subtypes.

The vaccine induces active immunity against Marek's disease, infectious bursal disease and avian influenza virus of the H5 subtype in chickens and turkeys. Antibodies against MDV, IBDV and AIV can therefore be detected after vaccination. Vaccination does not induce the development of antibodies against avian influenza neuraminidase or virus nucleoprotein; therefore, it is possible to distinguish vaccinated from infected birds through commercially available diagnostic tests.

## 5. PHARMACEUTICAL PARTICULARS

### 5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product, except the solvent supplied for use with the veterinary medicinal product.

### 5.2 Shelf life

Shelf life of the concentrate as packaged for sale: 3 years.
Shelf life of the solvent as packaged for sale: 3 years.
Shelf life after dilution according to directions: 2 hours.

### 5.3 Special precautions for storage

Store the vaccine in liquid nitrogen.
Discard any ampoules that have been accidentally thawed. Do not re-freeze under any circumstances.
Store the reconstituted vaccine at a temperature below 25 °C.
Do not re-use opened containers of reconstituted vaccine.
Store the solvent below 30 °C. Do not freeze. Protect from light.

### 5.4 Nature and composition of immediate packaging

Concentrate
One (type I glass) ampoule of 2 000 doses of vaccine.
Each ampoule is placed on carriers which are stored in canisters. The canisters are further stored in liquid nitrogen containers.

Solvent
Polyvinylchloride bag of 200 ml, 400 ml, 600 ml, 800 ml, 1 000 ml, 1 200 ml, 1 600 ml, 1 800 ml or 2 400 ml.

Not all pack sizes may be marketed.

### 5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

## 6. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH

## 7. MARKETING AUTHORISATION NUMBER(S)

EU/2/25/354/001

## 8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 19/11/2025.

## 9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

{DD/MM/YYYY}

**EXCEPTIONAL CIRCUMSTANCES:**
Marketing authorisation in exceptional circumstances and therefore assessment based on customised requirements for documentation. Only a limited assessment of quality, safety or efficacy has been conducted due to the lack of comprehensive quality, safety or efficacy data.

## 10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

**ANNEX II**

**OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION**

## OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

### SPECIFIC PHARMACOVIGILANCE REQUIREMENTS:

The MAH shall record in the pharmacovigilance database all results and outcomes of the signal management process, including a conclusion on the benefit-risk balance, according to the following frequency: annually.

### SPECIFIC OBLIGATION TO COMPLETE POST-AUTHORISATION MEASURES FOR THE MARKETING AUTHORISATION IN EXCEPTIONAL CIRCUMSTANCES

This being an approval in exceptional circumstances and pursuant to Article 25 of Regulation (EU) 2019/6, the MAH shall conduct, within the stated timeframe, the following measures:

| Description | Due date |
|---|---|
| The results of real time stability studies for the vaccine, up to 39 months, should be provided for at least 2 batches to confirm the 3-year shelf-life claim. Any out of specification detected should be communicated immediately to the European Medicines Agency. | December 2031 |

**ANNEX III**

**LABELLING AND PACKAGE LEAFLET**

# A. LABELLING

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

**GLASS AMPOULE**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vaxxitek HVT+IBD+H5

## 2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

2 000 

## 3. BATCH NUMBER

Lot {number}

## 4. EXPIRY DATE

Exp. {dd/mm/yyyy}

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING (LABEL) OF THE SOLVENT**

**BAG**

## 1. NAME OF THE SOLVENT

Solvent for cell associated poultry vaccines

## 2. TARGET SPECIES

Chickens and turkeys.

## 3. ROUTE(S) OF ADMINISTRATION

Read the package leaflet supplied with the vaccine before use.

Bag:
200 ml
400 ml
600 ml
800 ml
1 000 ml
1 200 ml
1 600 ml
1 800 ml
2 400 ml

## 4. EXPIRY DATE

Exp. {mm/yyyy}

## 5. SPECIAL STORAGE PRECAUTIONS

Store below 30 °C. Do not freeze. Protect from light.

## 6. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim

## 7. BATCH NUMBER

Lot {number}

# B. PACKAGE LEAFLET

# PACKAGE LEAFLET

## 1. Name of the veterinary medicinal product

Vaxxitek HVT+IBD+H5 concentrate and solvent for suspension for injection

## 2. Composition

Each dose of the reconstituted vaccine (0.2 ml for subcutaneous use or 0.05 ml for *in ovo* use) contains:

**Active substance:**
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: $\geq$ 3.6 to 4.4 $\log_{10}$ PFU*

*PFU: plaque forming unit.

Concentrate: yellow to reddish pink opalescent homogeneous suspension.
Solvent: red-orange limpid solution.

## 3. Target species

Chickens, turkeys and embryonated chicken eggs.

## 4. Indications for use

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

## 5. Contraindications

None.

## 6. Special warnings

Special warnings:
Vaccinate healthy animals only.
HVT maternally derived antibodies had no effect on HPAI H5 protection when the vaccine was administered by the subcutaneous route to one-day-old chicks and turkeys. It was not investigated with the *in ovo* route.

The effect of HPAI H5 maternally derived antibodies on the effect on HPAI H5 protection in chickens and turkeys has not yet been investigated.

Special precautions for safe use in the target species:
Apply the usual aseptic precautions to all administration procedures.
As a live vaccine, the vaccine strain is excreted from vaccinated chickens and turkeys and may spread to contact turkeys. Safety trials have shown that the strain is safe for turkeys. However, precautionary measures have to be followed in order to avoid direct or indirect contact between vaccinated chickens and turkeys.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Personal protective equipment consisting of gloves, spectacles and boots should be worn when handling the veterinary medicinal product, before withdrawing from liquid nitrogen, and during both the ampoule thawing and opening operations. Frozen glass ampoules may explode during sudden temperature changes. Store and use liquid nitrogen only in a dry and well-ventilated place. Inhalation of the liquid nitrogen is dangerous.

Laying birds:
This veterinary medicinal product is designed for one-day-old birds and 18-day-old embryonated chicken eggs therefore the safety of the veterinary medicinal product has not been established during lay.

Interaction with other medicinal products and other forms of interaction:
No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product. A decision to use this vaccine before or after any other veterinary medicinal product therefore needs to be made on a case-by-case basis.

Major incompatibilities:
Do not mix with any other veterinary medicinal product except the solvent supplied for use with the veterinary medicinal product.

## 7. Adverse events

Chickens and turkeys:

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or its local representative using the contact details at the end of this leaflet, or via your national reporting system: {national system details}

## 8. Dosage for each species, routes and method of administration

Subcutaneous or *in ovo* route.

For *in ovo* administration, an automated egg injection machine can be used. The device should be proven to safely and effectively deliver the appropriate dose. The instructions for use of this device should be strictly followed.

Subcutaneous route: one single injection of 0.2 ml per chicken or turkey at the age of one day.
*In ovo* route: one single injection of 0.05 ml per chicken egg at 18 days of embryonation.

## 9. Advice on correct administration

- Wear protective gloves, spectacles and boots during the ampoule thawing and opening operations. The handling of liquid nitrogen should take place in a well-ventilated area.
- Remove from the liquid nitrogen container only those ampoules which are to be used immediately.
- Thaw the contents of the ampoules rapidly by agitation in water at 25 °C - 30 °C. Proceed immediately to next step.
- As soon as they are thawed, open ampoules holding them at arm's length in order to prevent any risk of injury if any ampoule breaks.
- Select an appropriately sized sterile syringe to withdraw the vaccine from all the ampoules that are thawed and fit it with a needle of 18 gauge or larger.
- Gently insert the syringe needle through the septum of one of the bag's connecting tubes and withdraw 2 ml of solvent.
- Then draw up the complete contents of all the thawed ampoules into the syringe.
- Transfer the syringe contents into the solvent bag (do not use the solvent if it is cloudy).
- Gently mix the vaccine in the solvent bag by moving the bag back and forth.
- It is important to rinse the ampoules and ampoule tips. To do this, draw up a small volume of the solvent containing the vaccine into the syringe. Then slowly fill the ampoule bodies and tips with it. Withdraw the content from the ampoule bodies and tips and inject it back into the solvent bag.
- Repeat the thawing, opening, transfer and rinsing operations for the appropriate number of ampoules to be reconstituted in the solvent; either 1 ampoule of 2 000 doses of vaccine per 400 ml of solvent for subcutaneous administration, or 4 ampoules of 2 000 doses of vaccine per 400 ml of solvent for *in ovo* administration.
- The vaccine is a clear, red-orange coloured suspension ready for use. It should be mixed by gentle agitation and used immediately and up to two hours. During vaccination, gently swirl the bag frequently to ensure the vaccine remains homogenously mixed. Do not freeze it under any circumstances. Do not re-use opened containers of vaccine.

## 10. Withdrawal periods

Zero days.

## 11. Special storage precautions

Keep out of the sight and reach of children.

Store the vaccine in liquid nitrogen.
Discard any ampoules that have been accidentally thawed. Do not re-freeze under any circumstances.
Do not use this veterinary medicinal product after the expiry date which is stated on the ampoule after Exp.

Store the solvent below 30 °C. Do not freeze. Protect from light.

Shelf life after dilution according to directions: up to 2 hours at a temperature below 25 °C.
Do not re-use opened containers of reconstituted vaccine.

## 12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

## 13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

## 14. Marketing authorisation numbers and pack sizes

EU/2/25/354/001

Pack sizes:
Concentrate:
One (type I glass) ampoule of 2 000 doses of vaccine.
Each ampoule is placed on carriers which are stored in canisters. The canisters are further stored in liquid nitrogen containers.

Solvent:
Polyvinylchloride bag of 200 ml, 400 ml, 600 ml, 800 ml, 1 000 ml, 1 200 ml, 1 600 ml, 1 800 ml or 2 400 ml.

Not all pack sizes may be marketed.

## 15. Date on which the package leaflet was last revised

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

## 16. Contact details

Marketing authorisation holder:
Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
Germany

Manufacturers responsible for batch release:
Vaccine:
Boehringer Ingelheim Animal Health France SCS
Laboratoire Porte des Alpes
Rue de l'Aviation
69800 Saint-Priest
France

Solvent:
Laboratoire Bioluz
Zone Industrielle de Jalday
64500 Saint Jean de Luz
France

Boehringer Ingelheim Animal Health France SCS
Laboratoire Porte des Alpes
Rue de l'Aviation
69800 Saint-Priest
France

Local representatives and contact details to report suspected adverse events:

**België/Belgique/Belgien**
Boehringer Ingelheim Animal Health Belgium SA
Avenue Arnaud Fraiteurlaan 15-23,
BE-1050 Bruxelles/Brussel/Brüssel
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## 17. Other information

The vaccine strain is a recombinant herpesvirus of turkeys (HVT) expressing the protective antigen gene (VP2) of the infectious bursal disease virus (IBDV) strain Faragher 52/70 and a consensus haemagglutinin antigen gene of the avian influenza virus H5 subtypes.
The vaccine induces active immunity against Marek's disease, infectious bursal disease and avian influenza virus of the H5 subtype in chickens and turkeys. Antibodies against MDV, IBDV and AIV can therefore be detected after vaccination. Vaccination does not induce the development of antibodies against avian influenza neuraminidase or virus nucleoprotein; therefore, it is possible to distinguish vaccinated from infected birds through commercially available diagnostic tests.