SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vaxxitek HVT+IBD concentrate and solvent for suspension for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of vaccine contains:

Active substance:
Live vHVT013-69 recombinant virus, at least 3.6 to 4.4 log10 PFU*

Excipient:
Excipient qs 1 dose

Solvent:
Solvent qs 1 dose

*Plaque forming unit

3. PHARMACEUTICAL FORM

Concentrate: homogeneous suspension.
Solvent: red-orange limpid solution.

4. CLINICAL PARTICULARS

4.1 Target species

Day-old chickens and 18 days embryonated eggs.

4.2 Indications for use, specifying the target species

For active immunisation of chickens:

- To prevent mortality and to reduce clinical signs and lesions of Infectious Bursal disease.

  Onset of immunity: 2 weeks
  Duration of immunity: 9 weeks

- To reduce mortality, clinical signs and lesions of Marek's disease.

  Onset of immunity: 4 days
  Duration of immunity: a single vaccination is sufficient to provide protection during the risk period.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Vaccinate healthy animals only.

4.5 Special precautions for use

Special precautions for use in animals
Apply the usual aseptic precautions to all administration procedures.
As a live vaccine, the vaccine strain is excreted from vaccinated birds and may spread to turkeys. Safety and reversion to virulence 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
Wear protective gloves and spectacles during the ampoule thawing and opening operations.
Open ampoules holding them at arm's length in order to prevent any risk of injury should an ampoule break.

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

4.6 Adverse reactions (frequency and seriousness)

Chickens:

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.

4.7 Use during pregnancy, lactation or lay

Do not use in breeding birds and birds in lay.

4.8 Interaction with other medicinal products and other forms of interaction

For subcutaneous route:
Safety and efficacy data are available which demonstrate that this vaccine can be mixed with Boehringer Ingelheim attenuated vaccines against Marek's disease containing either Rispens (CVI988) strain or RN1250 strain. Chickens

with maternally derived antibodies against MD, when vaccinated with the mixed products, may have a delayed onset of immunity against infectious bursal disease.

Safety and efficacy data are available which demonstrate that this vaccine can be administered on the same day but not mixed with Boehringer Ingelheim attenuated vaccines against Newcastle disease and Infectious bronchitis.
No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except the products mentioned above. 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.

For *in ovo* route:
In the absence of specific studies, no other veterinary medicinal product should be administered concurrently with the product.

4.9 Amount(s) to be administered and administration route

Reconstitution of the vaccine

- Wear protective gloves and spectacles during the ampoule thawing and opening operations.
- Remove from the liquid nitrogen container only those ampoules which are to be used immediately. When this product is mixed with Marek's disease vaccine containing either Rispens (CVI988) strain or RN1250 strain, both should be diluted in the same solvent bag.
- 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 should an ampoule break.
- Once the ampoule is opened, draw up the contents into a 5 ml sterile syringe.
- Transfer the concentrate into the solvent (do not use if cloudy).
- Draw up 2 ml of the contents of the solvent into the syringe.
- Rinse the ampoule with these 2 ml and then transfer the rinsing liquid into the solvent. Repeat the rinsing operation once or twice.
- Repeat the thawing, opening, transfer and rinsing operations for the appropriate number of ampoules to be reconstituted in the solvent; either 1 ampoule of 1,000 doses of vaccine per 200 ml of solvent (or 1 ampoule of 2,000 doses of vaccine per 400 ml of solvent) for subcutaneous administration, or 4 ampoules of 1,000 doses of vaccine per 200 ml of solvent (or 4 ampoules of 2,000 doses of vaccines per 400 ml of solvent) for *in ovo* administration.

- The reconstituted vaccine prepared as described is mixed by gentle agitation so as to be ready for use. It should be used immediately after the preparation (all of the reconstituted vaccine should be used up within two hours). This is why the vaccine suspension should only be prepared as and when required.

  Posology
  One single injection of 0.2 ml per chicken 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.

  Method of administration
  The vaccine must be administered by subcutaneous route or 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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

None known.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

ATCvet Code: QI01AD15

Live recombinant vaccine against Infectious Bursal Disease and Marek's Disease.

The vaccine strain is a recombinant Herpesvirus of turkeys (HVT) expressing the protective antigen (VP2) of the Infectious Bursal Disease Virus (IBDV) strain Faragher 52/70.
The vaccine induces an active immunity and a serological response against Infectious Bursal Disease and Marek's Disease in chickens.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Concentrate:
Dimethyl sulfoxide
Dilution medium
Solvent:
Sucrose

Casein hydrolysate
Phenol red 1% solution
Salts

6.2 Major incompatibilities

Use sterile and antiseptic-free and/or disinfectant-free equipment for injections purposes.
Do not mix with any other veterinary medicinal product except the solvent supplied for use with the veterinary medicinal product and except those mentioned in section 4.8 above.

6.3 Shelf life

Shelf life of the concentrate as packaged for sale: 3 years at –196° C
Shelf life after reconstitution according to instructions: up to 2 hours at a temperature below 25° C.
Shelf life of the solvent in polypropylene bottles as packaged for sale: 1 year at a temperature below 30° C.
Shelf life of the solvent in polyvinylchloride bags as packaged for sale: 2 years at a temperature below 30°C.

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

6.5 Nature and composition of immediate packaging

Concentrate

- (glass) ampoule of 1 000 doses of vaccine, 5-ampoule carrier.
- (glass) ampoule of 2 000 doses of vaccine, 4-ampoule carrier.

Ampoule carriers are stored in canister, and in liquid nitrogen containers.

Solvent

- (polypropylene) bottle of 200 ml.
- (polyvinylchloride) bag of 200 ml, 400 ml, 600 ml, 800 ml, 1 000 ml, 1 200 ml, 1 400 ml, 1 600 ml, 1 800 ml or 2 400 ml.

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH
Binger Strasse 173
55216 Ingelheim am Rhein
Germany

8. MARKETING AUTHORISATION NUMBER

Vm 04491/5060

9. DATE OF FIRST AUTHORISATION

09 August 2002

10. DATE OF REVISION OF THE TEXT

July 2023

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' or 'PID' on www.gov.uk.

Approved 22 February 2024