SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vaxxitek HVT+IBD Suspension 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 .....qs 1 dose

Diluent:
Diluent.....qs 1 dose

*Plaque forming unit

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension and solvent for suspension for injection.

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.
  The onset of protection is from 2 weeks and the protection extends to 9 weeks.
- To reduce mortality, clinical signs and lesions of Marek's disease.
  The onset of protection is from 4 days. A single vaccination is sufficient to provide protection during the risk period.

4.3 Contraindications

Do not use in birds in lay and breeding birds.

4.4 Special warnings for each target species

Vaccinate only healthy birds.

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.

4.6 Adverse reactions (frequency and seriousness)

None known.

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 Amounts 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 suspension into the diluent (Do not use if cloudy).
- Draw up 2 ml of the contents of the diluent into the syringe.
- Rinse the ampoule with these 2 ml and then transfer the rinsing liquid into the diluent. 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 diluent; either 1 ampoule of 1,000 doses of vaccine per 200 ml of diluent (or 1 ampoule of 2,000 doses of vaccine per 400 ml of diluent) for subcutaneous administration, or 4 ampoules of 1,000 doses of vaccine per 200 ml of diluent (or 4 ampoules of 2,000 doses of vaccines per 400 ml of diluent) for *in ovo* administration.
- The diluted 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 diluted vaccine should be used up within one hour). 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

Suspension:
Dimethyl sulfoxide
Dilution medium

Diluent:
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 those mentioned in section 4.8 and the diluent supplied for use with the product.

6.3 Shelf life

Shelf life of the non-reconstituted vaccine: 36 months at –196°C
Shelf life of the reconstituted vaccine: up to 2 hours at a temperature below 25°C.
Shelf life of the diluent in polypropylene bottles: 12 months at a temperature below 30°C.
Shelf life of the diluent in polyvinylchloride bags: 24 months at a temperature below 30°C.

6.4 Special precautions for storage

Store the vaccine in liquid nitrogen.
Store the reconstituted vaccine at a temperature below 25°C.
Store the diluent below 30°C. Do not freeze. Protect from light.

6.5 Nature and composition of immediate packaging

- (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.
- (polypropylene) bottle of 200 ml of diluent
- (polyvinylchloride) bag of 200 ml, 400 ml, 600 ml, 800 ml, 1000 ml, 1200 ml, 1400 ml, 1600 ml, 1800 ml or 2400 ml of diluent.

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

Discard any ampoules that have been accidentally thawed. Do not re-freeze under any circumstances.
Do not re-use opened containers of diluted vaccine.

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

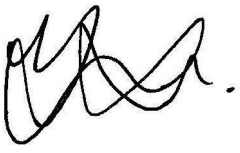
Vm 04491/5060

9. DATE OF FIRST AUTHORISATION

09 August 2002

10. DATE OF REVISION OF THE TEXT

May 2023



Approved: 10 May 2023