MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS (AMPOULE 1000 and 2000 doses)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vaxxitek HVT+IBD

2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)

1000
2000

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {dd/mm/yyyy}

5. ROUTE(S) OF ADMINISTRATION

SC / *in ovo*

6. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only

PARTICULARS TO APPEAR ON THE IMMEDIATE LABEL OF THE SOLVENT

1. NAME OF THE SOLVENT

Solvent for cell associated poultry vaccines

2. CONTENT BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

Bottle:
200 ml

Bag:
200 ml
400 ml
600 ml.
800 ml.
1000 ml
1200 ml
1400 ml
1600 ml
1800 ml
2400 ml

3. ROUTES OF ADMINISTRATION

Read the package leaflet supplied with the vaccine before use.

4. STORAGE CONDITIONS

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

5. BATCH NUMBER

Lot {number}

6. EXPIRY DATE

EXP {month/year}

7. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vaxxitek HVT+IBD concentrate and solvent for suspension for injection

2. COMPOSITION

Each dose of vaccine contains:

Active ingredient:

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

*Plaque forming unit

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

3. TARGET SPECIES

Day-old chickens and 18 days embryonated eggs.

4. INDICATIONS FOR USE

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.

5. CONTRAINDICATIONS

None.

6. SPECIAL WARNINGS

Special warnings:
Vaccinate healthy animals only.

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 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.

Laying birds:
Do not use in breeding birds and birds in lay.

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.

Use sterile and antiseptic-free and/or disinfectant-free equipment for injections purposes.

Major incompatibilities:
Do not mix with any other veterinary medicinal product except those mentioned in the above paragraph and the solvent supplied for use with the veterinary medicinal product.

7. ADVERSE EVENTS

Chickens:

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 the local representative of the marketing authorisation holder using the contact details at the end of this leaflet

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 at the age of one day.

In ovo route: one single injection of 0.05 ml per egg at 18 days of embryonation.

9. ADVICE ON CORRECT ADMINISTRATION

- 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 rapidly the contents of the ampoules 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 vaccine 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.

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.
Shelf life after reconstitution according to directions: up to 2 hours 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.

12. SPECIAL PRECAUTIONS FOR DISPOSAL

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.

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

Vm 04491/5060

Pack sizes:
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.

15. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED

July 2023

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

16. CONTACT DETAILS

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

Manufacturer(s) responsible for batch release:
Vaccine:
Boehringer Ingelheim Animal Health France SCS
Laboratoire Porte des Alpes
Rue de l'Aviation
69800 Saint-Priest
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Solvent:
Boehringer Ingelheim Animal Health France SCS
Laboratoire Porte des Alpes
Rue de l'Aviation
69800 Saint-Priest
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Laboratoire Bioluz
Zone Industrielle de Jalday
64500 Saint Jean de Luz

Local representatives and contact details to report suspected adverse reactions:

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17. OTHER INFORMATION

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.

POM-V Veterinary medicinal product subject to prescription

For animal treatment only

Approved 22 February 2024