ANNEX I

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

Excipients:

Qualitative composition of excipients and other constituents
Concentrate:
Dimethyl sulfoxide
Dilution medium
Solvent:
Sucrose
Casein hydrolysate
Phenol red 1% solution
Salts

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

3. CLINICAL INFORMATION

3.1 Target species

Day-old chickens and 18 days embryonated eggs.

3.2 Indications for use for each 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.

3.3 Contraindications

None.

3.4 Special warnings for each target species

Vaccinate healthy animals only.

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 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.

3.6 Adverse events

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.

3.7 Use during pregnancy, lactation or lay

Do not use in breeding birds and birds in lay.

3.8 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.

3.9 Administration routes and dosage

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.

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

Not applicable.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 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.

5. PHARMACEUTICAL PARTICULARS

5.1 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 3.8 above.

5.2 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: 3 years at a temperature below 30 °C.

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

5.4 Nature and composition of immediate packaging

Concentrate
- (glass) ampoule of 1 000 doses of vaccine.
- (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
- (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.

5.5 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 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/2/02/032/001-002

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 09/08/2002

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

{DD/MM/YYYY}

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

None.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

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. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

1000
2000

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {dd/mm/yyyy}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING (LABEL) OF THE DILUENT

(bottle or bag)

1. NAME OF THE DILUENT

Solvent for cell associated poultry vaccines

2. TARGET SPECIES

Chickens.

3. ROUTE(S) OF ADMINISTRATION

Read the package leaflet supplied with the vaccine before use.
Bottle:
200 ml

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

4. EXPIRY DATE

Exp. {month/year}

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 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, 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 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 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/2/02/032/001-002

Pack sizes:
Concentrate:
- (glass) ampoule of 1 000 doses of vaccine.
- (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:
- (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

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

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

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

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

Local representatives and contact details to report suspected adverse reactions:

België/Belgique/Belgien
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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.