

**ANNEX I**

**SUMMARY OF PRODUCT CHARACTERISTICS**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PREVEXXION RN+HVT+IBD concentrate and solvent for suspension for injection

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

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

### Active substances:

Marek's disease (MD) virus, serotype 1, strain RN1250 (cell-associated), live: 2.9 to 3.9 log<sub>10</sub> PFU\*

Turkey herpesvirus (HVT), strain vHVT013-69 (cell-associated), expressing the VP2 protein gene of infectious bursal disease (IBD), strain Faragher 52/70 virus, live: 3.6 to 4.4 log<sub>10</sub> PFU\*

\*PFU: plaque-forming units

### Excipients:

Qualitative composition of excipients and other constituents
<b>Vaccine concentrate:</b>
Dimethyl sulfoxide
199 Earle medium
Sodium hydrogen carbonate
Hydrochloric acid
Water for injections
<b>Solvent:</b>
Sucrose
Casein hydrolysate
Phenolsulfonphthalein (Phenol red)
Dipotassium phosphate
Potassium dihydrogen phosphate
Sodium hydroxide or hydrochloric acid
Water for injections

Concentrate: yellow to reddish pink opalescent homogeneous suspension.

Solvent: red-orange limpid solution.

## 3. CLINICAL INFORMATION

### 3.1 Target species

Chickens.

### 3.2 Indications for use for each target species

For active immunisation of one-day-old chicks or 18-day-old embryonated chicken eggs:

- to prevent mortality and clinical signs and reduce lesions caused by MD virus (including very virulent MD virus), and
- to prevent mortality and clinical signs and lesions caused by IBD (also known as Gumboro disease) virus.

Onset of immunity: MD: 5 days post-hatch.  
IBD: 14 days post-hatch (subcutaneous) or 28 days post-hatch (*in ovo*).

Duration of immunity: MD: A single vaccination is sufficient to provide protection for the entire risk period.  
IBD: 10 weeks post-hatch.

### 3.3 Contraindications

None.

### 3.4 Special warnings

Vaccinate healthy animals only.

Chickens with maternally derived antibodies against MD when vaccinated with this veterinary medicinal product, may have a delayed onset of immunity against IBD.

### 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 this is a live vaccine, both vaccine strains may be excreted from vaccinated birds. The RN1250 vaccine strain has not been shown to spread in experimental conditions. The vHVT013-69 vaccine strain may be spread to unvaccinated chickens and turkeys. Appropriate veterinary and husbandry measures should be taken to avoid spread of the vaccine strains to unvaccinated chickens, turkeys and other susceptible species.

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, during 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:

None.

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 chicks 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 and *in ovo* use.

Preparation of the vaccine suspension:

- 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.
- Preparation of the vaccine shall be planned before the ampoules are taken from the liquid nitrogen. The exact amount of vaccine ampoules and amount of solvent needed shall be calculated first according to the table below provided as example:

Solvent bag	Number of vaccine ampoules (subcutaneous use)	Number of vaccine ampoules ( <i>in ovo</i> use)
1 bag of 200 ml solvent	1 ampoule (1 000 doses)	4 ampoules (1 000 doses) or 2 ampoules (2 000 doses) or 1 ampoule (4 000 doses)
1 bag of 400 ml solvent	2 ampoules (1 000 doses) or 1 ampoule (2 000 doses)	8 ampoules (1 000 doses) or 4 ampoules (2 000 doses) or 2 ampoules (4 000 doses)
1 bag of 800 ml solvent	4 ampoules (1 000 doses) or 2 ampoules (2 000 doses) or 1 ampoule (4 000 doses)	16 ampoules (1 000 doses) or 8 ampoules (2 000 doses) or 4 ampoules (4 000 doses)

- Remove from the liquid nitrogen container only those ampoules, which are to be used immediately.
- Thaw the contents of the ampoules rapidly by gentle agitation in water at 25 °C — 30 °C. The thawing process should not exceed 90 seconds. Proceed immediately to the next step.
- As soon as they are thawed, wipe the ampoules with a clean paper towel and then open them while holding them at arm's length (in order to prevent 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.
- Tear the overpouch on the solvent bag, and then gently insert the syringe needle through the septum of one of the bag-connecting tubes and withdraw 2 ml of solvent.
- Then draw up the complete contents of all the thawed ampoules into the syringe. Do this by slowly drawing up the contents from each ampoule by gently tilting the ampoule forward and inserting the needle with the bevel edge facing downwards towards the bottom of the ampoule. Continue until all the vaccine is drawn out of the ampoule.
- 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 this rinsing operation once.
- Repeat the thawing, opening, transfer and rinsing operations for the appropriate number of ampoules to be diluted in the solvent bag.
- The vaccine is ready for use and should be mixed by gentle agitation and used immediately. During vaccination, gently swirl the bag frequently to ensure the vaccine remains homogenously mixed.
- The vaccine is a clear, red-orange coloured suspension for injection to be used within two hours. Do not freeze it under any circumstances. Do not re-use opened containers of vaccine.

Posology:

One single injection of 0.2 ml per one-day-old chick or 0.05 ml per 18-day-old embryonated chicken egg.

Method of administration:

The vaccine must be administered by subcutaneous injection in the neck or by *in ovo* injection.

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

A limited and transient effect on growth was observed when 10-fold maximum release dose was administered subcutaneously to White Leghorn specified pathogen free chickens.

### **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**

The vaccine contains the recombinant viruses RN1250 and vHVT013-69 within chicken embryo cells. The RN1250 virus is an engineered MD virus composed of three serotype 1 strains. Its genome also contains long terminal repeats of reticuloendotheliosis virus. The vHVT013-69 virus is a recombinant HVT expressing the protective antigen (VP2) of the IBD virus strain Faragher 52/70.

The vaccine induces an active immunity and a serological response against Marek's disease and IBD in chickens.

## **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 veterinary medicinal product 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 at a temperature below 25 °C.

## **5.3 Special precautions for storage**

Vaccine concentrate:

Store and transport frozen in liquid nitrogen.

The liquid nitrogen containers must be checked regularly for liquid nitrogen level and must be refilled as needed.

Discard any ampoules that have been accidentally thawed.

Solvent:

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

## **5.4 Nature and composition of immediate packaging**

Vaccine concentrate:

- Type I glass ampoule of 1 000 doses of vaccine.
- Type I glass ampoule of 2 000 doses of vaccine.
- Type I glass ampoule of 4 000 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 containing 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/2/20/255/001-003

## **8. DATE OF FIRST AUTHORISATION**

Date of first authorisation: 20 July 2020

**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**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

PREVEXXION RN+HVT+IBD

**2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES**

1 000  
2 000  
4 000



**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.

**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**



**7. BATCH NUMBER**

Lot {number}

## **B. PACKAGE LEAFLET**

## PACKAGE LEAFLET

### 1. Name of the veterinary medicinal product

PREVEXXION RN+HVT+IBD concentrate and solvent for suspension for injection

### 2. Composition

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

#### Active substances:

Marek's disease (MD) virus, serotype 1, strain RN1250 (cell-associated), live: 2.9 to 3.9 log<sub>10</sub> PFU\*


Turkey herpesvirus (HVT), strain vHVT013-69 (cell-associated), expressing the VP2 protein gene of infectious bursal disease (IBD), strain Faragher 52/70 virus, live: 3.6 to 4.4 log<sub>10</sub> PFU\*

\*PFU: plaque-forming units

Concentrate: yellow to reddish pink opalescent homogeneous suspension

Solvent: red-orange limpid solution.

### 3. Target species

Chickens. 

### 4. Indications for use

For active immunisation of one-day-old chicks or 18-day-old embryonated chicken eggs:

- to prevent mortality and clinical signs and reduce lesions caused by MD virus (including very virulent MD virus), and
- to prevent mortality and clinical signs and lesions caused by IBD (also known as Gumboro disease) virus.

Onset of immunity: MD: 5 days post-hatch.  
IBD: 14 days post-hatch (subcutaneous) or 28 days post-hatch (*in ovo*).

Duration of immunity: MD: A single vaccination is sufficient to provide protection for the entire risk period.  
IBD: 10 weeks post-hatch.

### 5. Contraindications

None.

## **6. Special warnings**

### Special warnings:

Vaccinate healthy animals only.

Chickens with maternally derived antibodies against MD when vaccinated with this veterinary medicinal product, may have a delayed onset of immunity against IBD.

### Special precautions for safe use in the target species:

Apply the usual aseptic precautions to all administration procedures.

As this is a live vaccine, both vaccine strains may be excreted from vaccinated birds. The RN1250 vaccine strain has not been shown to spread in experimental conditions. The vHVT013-69 vaccine strain may be spread to unvaccinated chickens and turkeys. Appropriate veterinary and husbandry measures should be taken to avoid spread of the vaccine strains to unvaccinated chickens, turkeys and other susceptible species.

### 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, during 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 chicks 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.

### Overdose:

A limited and transient effect on growth was observed when 10-fold maximum release dose was administered subcutaneously to White Leghorn specified pathogen free chickens.

### 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:

None.

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 (s.c.) or *in ovo* route.

One single injection of 0.2 ml per one-day-old chick or 0.05 ml per 18-day-old embryonated chicken egg.

The vaccine must be administered by subcutaneous injection in the neck or by *in ovo* injection.

## 9. Advice on correct administration

### Preparation of the vaccine suspension:

- 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.
- Preparation of the vaccine shall be planned before the ampoules are taken from the liquid nitrogen. The exact amount of vaccine ampoules and amount of solvent needed shall be calculated first according to the table below provided as example:

Solvent bag	Number of vaccine ampoules (subcutaneous use)	Number of vaccine ampoules ( <i>in ovo</i> use)
1 bag of 200 ml solvent	1 ampoule (1 000 doses)	4 ampoules (1 000 doses) or 2 ampoules (2 000 doses) or 1 ampoule (4 000 doses)
1 bag of 400 ml solvent	2 ampoules (1 000 doses) or 1 ampoule (2 000 doses)	8 ampoules (1 000 doses) or 4 ampoules (2 000 doses) or 2 ampoules (4 000 doses)
1 bag of 800 ml solvent	4 ampoules (1 000 doses) or 2 ampoules (2 000 doses) or 1 ampoule (4 000 doses)	16 ampoules (1 000 doses) or 8 ampoules (2 000 doses) or 4 ampoules (4 000 doses)

- Remove from the liquid nitrogen container only those ampoules, which are to be used immediately.
- Thaw the contents of the ampoules rapidly by gentle agitation in water at 25 °C — 30 °C. The thawing process should not exceed 90 seconds. Proceed immediately to the next step.
- As soon as they are thawed, wipe the ampoules with a clean paper towel and then open them while holding them at arm's length (in order to prevent 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.
- Tear the overpouch on the solvent bag, and then gently insert the syringe needle through the septum of one of the bag-connecting tubes and withdraw 2 ml of solvent.
- Then draw up the complete contents of all the thawed ampoules into the syringe. Do this by slowly drawing up the contents from each ampoule by gently tilting the ampoule forward and inserting the needle with the bevel edge facing downwards towards the bottom of the ampoule. Continue until all the vaccine is drawn out of the ampoule.
- 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 this rinsing operation once.



- Repeat the thawing, opening, transfer and rinsing operations for the appropriate number of ampoules to be diluted in the solvent bag.
- The vaccine is ready for use and should be mixed by gentle agitation and used immediately. During vaccination, gently swirl the bag frequently to ensure the vaccine remains homogeneously mixed.
- The vaccine is a clear, red-orange coloured suspension for injection to be used within two hours. Do not freeze the vaccine 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.

##### Vaccine concentrate:

Store and transport frozen in liquid nitrogen.

The liquid nitrogen containers must be checked regularly for liquid nitrogen level and must be refilled as needed.

##### Solvent:

Store below 30 °C.

Do not freeze.

Protect from light.

Shelf life after dilution according to directions: 2 hours at a temperature below 25 °C.

Do not use the vaccine after the expiry date which is stated on the ampoule after Exp.

Discard any ampoules that have been accidentally thawed. Do not re-freeze under any circumstances.

Do not re-use opened containers of 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 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/2/20/255/001-003

Package sizes:

Frozen vaccine concentrate:

- Type I glass ampoule of 1 000 doses of vaccine.
- Type I glass ampoule of 2 000 doses of vaccine.
- Type I glass ampoule of 4 000 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**

{MM/YYYY}

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:

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 events:

**België/Belgique/Belgien**

Boehringer Ingelheim Animal  
Health Belgium SA  
Avenue Arnaud Fraiteurlaan 15-23,  
BE-1050 Bruxelles/Brussel/Brüssel  
Tél/Tel: + 32 2 773 34 56

**Република България**

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**Česká republika**

Boehringer Ingelheim spol. s r.o.  
Purkyňova 2121/3  
CZ-110 00, Praha 1  
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**Danmark**

Boehringer Ingelheim Animal Health Nordics  
A/S  
Weidekampsgade 14  
DK-2300 København S  
Tlf: + 45 3915 8888

**Deutschland**

Boehringer Ingelheim Vetmedica GmbH  
DE-55216 Ingelheim/Rhein  
Tel: 0800 290 0 270

**Eesti**

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Eesti filiaal  
Dr. Boehringer Gasse 5-11  
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**Ελλάδα**

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**España**

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Tel: +34 93 404 51 00

**Lietuva**

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**Luxembourg/Luxemburg**

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**Magyarország**

Boehringer Ingelheim RCV GmbH & Co KG  
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**Malta**

Boehringer Ingelheim Vetmedica GmbH  
DE-55216 Ingelheim/Rhein  
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**Nederland**

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NL-1043 AP Amsterdam  
Tel: +31 20 799 6950

**Norge**

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**Österreich**

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PL-00-728 Warszawa  
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**France**

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SCS  
29, avenue Tony Garnier  
FR-69007 Lyon  
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**Hrvatska**

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**Ireland**

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**Κύπρος**

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**Latvija**

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**Portugal**

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**România**

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**Slovenija**

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**Slovenská republika**

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**Suomi/Finland**

Vetcare Oy  
PB 99  
FI-24101 Salo  
Puh/Tel: + 358 201443360

**Sverige**

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**United Kingdom (Northern Ireland)**

Boehringer Ingelheim Vetmedica GmbH  
DE-55216 Ingelheim/Rhein  
Tel: +353 1 291 3985

## **17. Other information**

The vaccine contains the recombinant viruses RN1250 and vHVT013-69 within chicken embryo cells. The RN1250 virus is an engineered MD virus composed of three serotype 1 strains. Its genome also contains long terminal repeats of reticuloendotheliosis virus.

The vHVT013-69 virus is a recombinant HVT expressing the protective antigen (VP2) of the IBD virus strain Faragher 52/70.

The vaccine induces an active immunity and a serological response against Marek's disease and IBD in chickens.