ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PREVEXXION RN concentrate and solvent for suspension for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 0.2 ml dose of the vaccine suspension contains:

Active substance:
Cell-associated live recombinant Marek's disease (MD) virus, serotype 1, strain RN1250 2.9 to 3.9 $\log_{10}$ PFU*

*PFU: plaque forming units.

Excipients:

Qualitative composition of excipients and other constituents:
Frozen vaccine concentrate:
Dimethyl sulfoxide
199 Earle medium
Sodium hydrogen carbonate
Hydrochloric acid
Water for injections
Solvent:
Sucrose
Casein hydrolysate
Phenolsulfonphthalein (Phenol red)
Dipotassium phosphate
Potassium dihydrogen phosphate
Sodium hydroxide or hydrochloric acid (for pH adjustment)
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 to prevent mortality and clinical signs and reduce lesions caused by MD virus (including very virulent MD virus).

Onset of immunity: 5 days after vaccination.

Duration of immunity: A single vaccination is sufficient to provide protection for the entire risk period.

3.3 Contraindications

None.

3.4 Special warnings

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 this is a live vaccine, the vaccine strain may be excreted from vaccinated birds, but it has not been shown to spread in experimental conditions.
Nevertheless, appropriate veterinary and husbandry measures should be taken to avoid spread of the vaccine strain to unvaccinated chickens 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, and during both 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 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

This veterinary medicinal product is designed for one-day-old chicks and 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

Safety and efficacy data are available which demonstrate that this vaccine can be mixed and administered with Vaxxitek HVT+IBD. Chickens with maternally derived antibodies against MD, when vaccinated with the mixed products, may have a delayed onset of immunity against infectious bursal disease (also known as Gumboro disease). The mixed vaccine suspension is not intended for the immunization of embryonated eggs.
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 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. When this product is mixed with Vaxxitek HVT+IBD, both should be diluted in the same solvent bag as indicated below.

Solvent bag	Number of Prevexxion RN ampoules	Number of Vaxxitek HVT+IBD ampoules
1 x 200 ml	1 x 1,000 doses	1 x 1,000 doses
1 x 400 ml	2 x 1,000 doses or 1 x 2,000 doses	2 x 1,000 doses or 1 x 2,000 doses
1 x 800 ml	4 x 1,000 doses or 2 x 2,000 doses or 1 x 4,000 doses	4 x 1,000 doses or 2 x 2,000 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. Do not use the solvent if cloudy.
- 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
- 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.

Method of administration:
The vaccine must be administered by subcutaneous injection in the neck.

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 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: QI01AD03

Pharmacotherapeutic group: Immunologicals for Aves, live viral vaccines.

The vaccine contains the recombinant virus RN1250 within chicken embryo cells.
The vaccine is an engineered MD virus composed of three serotype 1 strains. Its genome also contains long terminal repeats of reticuloendotheliosis virus. The vaccine induces an active immunity against Marek's disease in chickens.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product, except those mentioned in section 3.8 and 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: 2 years.
Shelf life after vaccine preparation 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, 5-ampoule carrier.
- Type I glass ampoule of 2,000 doses of vaccine, 5-ampoule carrier.
- Type I glass ampoule of 4,000 doses of vaccine, 4-ampoule carrier.

The ampoule carriers are stored firstly in canisters, and these canisters are then stored latter in the 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 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/2/20/254/001-003

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 20/07/2020

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

{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

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 PACKAGE (LABEL) OF THE DILUENT

BAG

1. NAME OF THE DILUENT

Solvent for cell associated poultry vaccines

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

200 ml
400 ml
600 ml
800 ml
1000 ml
1200 ml
1600 ml
1800 ml
2400 ml

3. ROUTE(S) 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.

Boehringer Ingelheim

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

PREVEXXION RN concentrate and solvent for suspension for injection

2. Composition

Each 0.2 ml dose of the vaccine suspension contains:

Active substance:
Cell-associated live recombinant Marek's disease (MD) virus, serotype 1, strain RN1250 2.9 to 3.9 $\log_{10}$ 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 to prevent mortality and clinical signs and reduce lesions caused by MD virus (including very virulent MD virus).

Onset of immunity: 5 days after vaccination.
Duration of immunity: A single vaccination is sufficient to provide protection for the entire risk period.

5. Contraindications

None.

6. 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 this is a live vaccine, the vaccine strain may be excreted from vaccinated birds, but it has not been shown to spread in experimental conditions. Nevertheless, appropriate veterinary and husbandry measures should be taken to avoid spread of the vaccine strain to unvaccinated chickens 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, and during both

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 therefore the safety of the veterinary medicinal product has not been established during lay.

Interaction with other medicinal products and other forms of interaction:
Safety and efficacy data are available which demonstrate that this vaccine can be mixed and administered with Vaxxitek HVT+IBD. Chickens with maternally derived antibodies against MD, when vaccinated with the mixed products, may have a delayed onset of immunity against infectious bursal disease (also known as Gumboro disease). The mixed vaccine suspension is not intended for the immunization of embryonated eggs.
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 to White Leghorn specified pathogen free chickens.

Major incompatibilities:
Do not mix with any other veterinary medicinal product, except those mentioned in section "Interaction" 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.

8. Dosage for each species, routes and method of administration

One single injection of 0.2 ml per one-day-old chick.
The vaccine must be administered by subcutaneous injection in the neck.

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. When this product is mixed with Vaxxitek HVT+IBD, both should be diluted in the same solvent bag as indicated below.

Solvent bag	Number of Prevexxion RN ampoules	Number of Vaxxitek HVT+IBD ampoules
1 x 200 ml	1 x 1,000 doses	1 x 1,000 doses
1 x 400 ml	2 x 1,000 doses or 1 x 2,000 doses	2 x 1,000 doses or 1 x 2,000 doses
1 x 800 ml	4 x 1,000 doses or 2 x 2,000 doses or 1 x 4,000 doses	4 x 1,000 doses or 2 x 2,000 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. Do not use the solvent if cloudy.
- 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.
- 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 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.
The vaccine concentrate must be stored and transported frozen in liquid nitrogen.
The liquid nitrogen containers must be checked regularly for liquid nitrogen level and must be refilled as needed.
Solvent must be stored at a temperature below 30 °C.
Do not freeze.
Protect from light.
Shelf life after vaccine preparation 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 applicable national collection systems. These measures should help to protect the environment.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

EU/2/20/254/001-003

Pack sizes:
Frozen vaccine concentrate:
- Type I glass ampoule of 1,000 doses of vaccine, 5-ampoule carrier.
- Type I glass ampoule of 2,000 doses of vaccine, 5-ampoule carrier.
- Type I glass ampoule of 4,000 doses of vaccine, 4-ampoule carrier.

The ampoule carriers are stored firstly in canisters, and these canisters are then stored latter in the 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

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
Boehringer Ingelheim Animal
Health Belgium SA
Avenue Arnaud Fraiteurlaan 15-23,
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17. Other information

The vaccine contains the recombinant virus RN1250 within chicken embryo cells.
The vaccine is an engineered MD virus composed of three serotype 1 strains. Its genome also contains long terminal repeats of reticuloendotheliosis virus. The vaccine induces an active immunity against Marek's disease in chickens.