ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Innovax-ND-IBD concentrate and solvent for suspension for injection for chickens

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

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

Active substance:
Cell-associated live recombinant turkey herpesvirus (strain HVP360), expressing the fusion protein of Newcastle disease virus and the VP2 protein of infectious bursal disease virus: $10^{3.3}$ – $10^{4.6}$ PFU[1].

[1] PFU – plaque forming units.

Excipients:
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Concentrate and solvent for suspension for injection.

Cell concentrate: off-red to red cell concentrate.
Solvent: clear, red solution.

4. CLINICAL PARTICULARS

4.1 Target species

Chickens and embryonated chicken eggs.

4.2 Indications for use, specifying the target species

For active immunisation of one-day-old chicks or 18–19 day-old embryonated chicken eggs:
- to reduce mortality and clinical signs caused by Newcastle disease (ND) virus,
- to prevent mortality and to reduce clinical signs and lesions caused by infectious bursal disease (IBD) virus,
- to reduce mortality, clinical signs and lesions caused by Marek's disease (MD) virus.

Onset of immunity: ND: 4 weeks of age,
IBD: 3 weeks of age,
MD: 9 days.

Duration of immunity: ND: 60 weeks,
IBD: 60 weeks,
MD: entire risk period.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Vaccinate healthy animals only.

4.5 Special precautions for use

Special precautions for use in animals

As this is a live vaccine, the vaccine strain is excreted from vaccinated birds and may spread to turkeys. Safety 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

The handling of liquid nitrogen should take place in a well-ventilated area.
Innovax-ND-IBD is a virus suspension packed in glass ampoules and stored in liquid nitrogen. Before withdrawing ampoules from the liquid nitrogen canister, protective equipment consisting of gloves, long sleeves and a facemask or goggles should be worn. In order to prevent serious wounds, by either the liquid nitrogen or the ampoules when removing an ampoule from the canister, hold the palm of the (gloved) hand holding the ampoule away from the body and face. Care should be exercised to prevent contaminating the hands, eyes and clothing with the ampoule content. CAUTION: The ampoules have been known to explode on exposure to sudden temperature changes. Do not thaw in hot water or ice-cold water. Thaw the ampoules in clean water at 25–27 °C.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

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

4.8 Interaction with other medicinal products and other forms of interaction

Safety and efficacy data are available which demonstrate that Innovax-ND-IBD can be mixed in the same solvent and administered by the subcutaneous route with Nobilis Rismavac. For this mixed use, an onset of immunity of 5 days has been demonstrated for MD.

Safety and efficacy data are available which demonstrate that Nobilis ND Clone 30 or Nobilis ND C2 can be administered to day-old chicks that are vaccinated either by the subcutaneous or *in ovo* route with Innovax-ND-IBD. For such associated use, an onset of immunity of 3 weeks (when used with Nobilis ND Clone 30) and 2 weeks (when used with Nobilis ND C2), has been demonstrated for ND.
Safety and efficacy data are available which demonstrate that Nobilis IB Ma5 or Nobilis IB 4-91 can be administered to day-old chicks that are vaccinated either by the subcutaneous or *in ovo* route with the vaccine.

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.

4.9 Amounts to be administered and administration route

Subcutaneous use and *in ovo* use.

Preparation of the vaccine:
The usual aseptic precautions should be applied to all preparation and administration procedures. The handling of liquid nitrogen should take place in a well-ventilated area.
1. Use solvent for cell associated poultry vaccines for reconstitution.

For subcutaneous use reconstitute the vaccine according to the table below:

Solvent bag	Number of vaccine ampoules for subcutaneous use
Bag of 400 ml solvent	1 ampoule containing 2000 doses
Bag of 800 ml solvent	2 ampoules containing 2000 doses
Bag of 800 ml solvent	1 ampoule containing 4000 doses
Bag of 1200 ml solvent	3 ampoules containing 2000 doses
Bag of 1600 ml solvent	4 ampoules containing 2000 doses
Bag of 1600 ml solvent	2 ampoules containing 4000 doses

When this product is mixed with Nobilis Rismavac, both should be diluted in the same solvent bag in the same way (400 ml of solvent for each 2,000 doses of both products or 800 ml of solvent for each 4,000 doses of both products).

For *in ovo* use reconstitute the vaccine according to the table below:

Solvent bag	Number of vaccine ampoules for *in ovo* use
Bag of 400 ml solvent	4 ampoules containing 2000 doses
Bag of 400 ml solvent	2 ampoules containing 4000 doses
Bag of 800 ml solvent	8 ampoules containing 2000 doses
Bag of 800 ml solvent	4 ampoules containing 4000 doses
Bag of 1200 ml solvent	12 ampoules containing 2000 doses
Bag of 1200 ml solvent	6 ampoules containing 4000 doses
Bag of 1600 ml solvent	16 ampoules containing 2000 doses
Bag of 1600 ml solvent	8 ampoules containing 4000 doses

The solvent must be clear, red coloured, without sediment and at room temperature (15–25 °C) at the time of mixing.

2. Preparation of the vaccine shall be planned before the ampoules are taken from the liquid nitrogen and the exact amount of vaccine ampoules and amount of solvent needed shall be calculated first. There is no information available on the number of doses on the ampoules once they are removed from the cane, so special care has to be taken to ensure that the mix-ups of ampoules with different number of doses is avoided and the correct solvent is used.
3. Before withdrawing the ampoules from the liquid nitrogen container, protect the hands with gloves, wear long sleeves and use a facemask or goggles. When removing an ampoule from the cane, hold in the palm of a gloved hand away from the body and the face.
4. When withdrawing a cane of ampoules from the canister in the liquid nitrogen container, expose only the ampoule(s) to be used immediately. It is recommended to handle a maximum of 5 ampoules (from one cane only) at a time. After removing the ampoule(s), the remaining ampoules should be put back immediately into the canister in the liquid nitrogen container.
5. Thaw the content of the ampoule(s) rapidly by immersing the ampoule in clean water at 25–27 °C. Gently swirl the ampoule(s) to disperse the contents. In order to protect the cells, it is important that the ampoule content is mixed, immediately after thawing, with the solvent. Dry the ampoule, then break the ampoule at its neck and immediately proceed as described below.
6. Gently withdraw the contents of the ampoule into a sterile syringe fitted with an 18 gauge needle.
7. Insert the needle through the stopper of the solvent bag, and then slowly and gently add the contents of the syringe to the solvent. Gently swirl and invert the bag to mix the vaccine. Withdraw a small quantity from the solvent bag into the syringe and rinse the ampoule. Inject the remaining contents of the ampoule gently into the solvent bag. Remove the syringe and invert the bag (6–8 times) to mix the vaccine.
8. The vaccine is now ready for use.
   After adding the contents of the ampoule to the solvent, the ready to use product is a clear, red coloured suspension for injection.

Posology:
Subcutaneous: One single injection of 0.2 ml per chick.
In ovo: One single injection of 0.05 ml per chicken egg.

Administration:
The vaccine is administered by subcutaneous injection in the neck or by *in ovo* injection. The bag of vaccine should be gently swirled frequently during vaccination to guarantee that the vaccine suspension remains homogenous and that the correct vaccine virus titre is administered (e.g. during long vaccination sessions).

Control of correct storage:
To allow a check on correct storage and transport the ampoules are placed upside down in the liquid nitrogen containers. If frozen content is situated in the tip of the ampoule this indicates that the content has been thawed and must not be used.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

No symptoms were observed after the administration of a 10-fold dose of vaccine when applied subcutaneously. A 3-fold overdose was tested *in ovo*, which was regarded as safe. No information is available on the safety or possible adverse reactions following a 10-fold overdose applied *in ovo*.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for aves, live viral vaccines for domestic fowls.
ATCvet code: QI01AD16.

The vaccine is a cell-associated live recombinant turkey herpesvirus (HVT) expressing the F protein of Newcastle disease virus and the VP2 protein of infectious bursal disease virus. The vaccine induces active immunity against Newcastle disease, infectious bursal disease (Gumboro disease) and Marek's disease in chickens.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cell concentrate
Bovine serum
Veggie medium
Dimethyl sulfoxide

Solvent:
Sucrose
Sodium chloride
Disodium hydrogen phosphate dihydrate
Phenolsulfonphthalein (Phenol red)
Potassium dihydrogen phosphate
Water for injections

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal product, except Nobilis Rismavac and the solvent supplied for use with this medicinal product.

6.3 Shelf life

Shelf life of the cell concentrate as packaged for sale: 2 years.
Shelf life of the solvent (multilayer plastic bags) as packaged for sale: 3 years.
Shelf life after reconstitution according to directions: 2 hours.

6.4 Special precautions for storage

Cell concentrate:
Store and transport frozen in liquid nitrogen (below -140 °C).

Solvent:
Store below 30 °C.

Container:
Store liquid nitrogen container securely in an upright position in a clean, dry and well-ventilated room separated from the hatching/chicken room.

6.5 Nature and composition of immediate packaging

Cell concentrate:
- One Type I glass ampoule of 2 ml containing 2,000 or 4,000 doses. Ampoules are stored on a cane and attached to the cane is a coloured clip displaying the dose (2,000 doses: salmon-pink coloured clip, and 4,000 doses: yellow coloured clip).

Solvent:
- One 400 ml multilayer plastic bag.
- One 800 ml multilayer plastic bag.
- One 1200 ml multilayer plastic bag.
- One 1600 ml multilayer plastic bag.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

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

Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
THE NETHERLANDS

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/17/213/001-002

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 22/08/2017

10. DATE OF REVISION OF THE TEXT

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (http://www.ema.europa.eu/).

PROHIBITION OF SALE, SUPPLY AND/OR USE

Any person intending to manufacture, import, possess, sell, supply and use this veterinary medicinal product must first consult the relevant Member State's competent authority on the current vaccination policies, as these activities may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation.

ANNEX II

A. MANUFACTURERS OF THE BIOLOGICAL ACTIVE SUBSTANCES AND MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

C. STATEMENT OF THE MRLs

A. MANUFACTURERS OF THE BIOLOGICAL ACTIVE SUBSTANCE AND MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturers of the biological active substance

Intervet International B.V.
Ambachtstraat 2-6
3732 CN De Bilt
THE NETHERLANDS

Intervet Inc.
29160 Intervet Lane
PO Box 318, Millsboro
Delaware 19966-0318
UNITED STATES OF AMERICA

Name and address of the manufacturer responsible for batch release

Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
THE NETHERLANDS

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription.

According to Article 71 of Directive 2001/82/EC of the European Parliament and of the Council as amended, a Member State may, in accordance with its national legislation, prohibit the manufacture, import, possession, sale, supply and/or use of immunological veterinary medicinal products on the whole or part of its territory if it is established that:

a) the administration of the product to animals will interfere with the implementation of a national programme for the diagnosis, control or eradication of animal diseases, or will cause difficulties in certifying the absence of contamination in live animals or in foodstuffs or other products obtained from treated animals.

b) the disease to which the product is intended to confer immunity is largely absent from the territory in question.

Official control authority batch release is required for this product.

C. STATEMENT OF THE MRLs

The active substance being a principle of biological origin intended to produce active immunity is not within the scope of Regulation (EC) No 470/2009.

The excipients (including adjuvants) listed in section 6.1 of the SPC are either allowed substances for which table 1 of the annex to Commission Regulation (EU) No 37/2010 indicates that no MRLs are required or considered as not falling within the scope of Regulation (EC) No 470/2009 when used as in this veterinary medicinal product.

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

Innovax-ND-IBD

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

HVP360

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

2,000
4,000
(number of doses per ampoule is presented on the colour coded clip attached to each cane containing the ampoule)

4. ROUTE(S) OF ADMINISTRATION

SC
In ovo

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Lot

7. EXPIRY DATE

EXP

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

[please note; the sentence 'for animal treatment only' will only appear in English and will not be translated]

MSD Animal Health Logo

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

SOLVENT BAG

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Solvent for cell associated poultry vaccines.

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

400 ml
800 ml
1200 ml
1600 ml

3. ROUTE(S) OF ADMINISTRATION

Read package leaflet before use.

4. STORAGE CONDITIONS

Store below 30°C.

5. BATCH NUMBER

Lot

6. EXPIRY DATE

EXP

7. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Innovax-ND-IBD concentrate and solvent for suspension for injection for chickens

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder and manufacturer responsible for batch release:
Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
THE NETHERLANDS

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Innovax-ND-IBD concentrate and solvent for suspension for injection for chickens

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each dose of the reconstituted vaccine (0.2 ml for subcutaneous use or 0.05 ml for *in ovo* use) contains:
Cell-associated live recombinant turkey herpesvirus (strain HVP360), expressing the fusion protein of Newcastle disease virus and the VP2 protein of infectious bursal disease virus: $10^{3.3}$ – $10^{4.6}$ PFU[1].

[1] PFU – plaque forming units.

Concentrate and solvent for suspension for injection.
Cell concentrate: off-red to red cell concentrate.
Solvent: clear, red solution.

4. INDICATION(S)

For active immunisation of one-day-old chicks or 18–19 day-old embryonated chicken eggs:
- to reduce mortality and clinical signs caused by Newcastle disease (ND) virus,
- to prevent mortality and to reduce clinical signs and lesions caused by infectious bursal disease (IBD) virus,
- to reduce mortality, clinical signs and lesions caused by Marek's disease (MD) virus.

Onset of immunity: ND: 4 weeks of age,
IBD: 3 weeks of age,
MD: 9 days.

Duration of immunity: ND: 60 weeks,
IBD: 60 weeks,
MD: entire risk period.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

None known.

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 inform your veterinary surgeon.

7. TARGET SPECIES

Chickens and embryonated chicken eggs.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

After dilution, administer 1 dose of 0.2 ml vaccine per chicken by subcutaneous injection in the neck or 1 dose of 0.05 ml per egg by *in ovo* injection.

9. ADVICE ON CORRECT ADMINISTRATION

The bag of vaccine should be gently swirled frequently during vaccination to guarantee that the vaccine suspension remains homogenous and that the correct vaccine virus titre is administered (e.g. during long vaccination sessions).

Preparation of the vaccine:
The usual aseptic precautions should be applied to all preparation and administration procedures.
The handling of liquid nitrogen should take place in a well-ventilated area.

1. Use solvent for cell associated poultry vaccines for reconstitution.

   For subcutaneous use reconstitute the vaccine according to the table below:

Solvent bag	Number of vaccine ampoules for subcutaneous use
Bag of 400 ml solvent	1 ampoule containing 2000 doses
Bag of 800 ml solvent	2 ampoules containing 2000 doses
Bag of 800 ml solvent	1 ampoule containing 4000 doses
Bag of 1200 ml solvent	3 ampoules containing 2000 doses
Bag of 1600 ml solvent	4 ampoules containing 2000 doses
Bag of 1600 ml solvent	2 ampoules containing 4000 doses

   When this product is mixed with Nobilis Rismavac, both should be diluted in the same solvent bag in the same way (400 ml of solvent for each 2,000 doses of both products or 800 ml of solvent for each 4,000 doses of both products).

   For *in ovo* use reconstitute the vaccine according to the table below:

Solvent bag	Number of vaccine ampoules for *in ovo* use
Bag of 400 ml solvent	4 ampoules containing 2000 doses
Bag of 400 ml solvent	2 ampoules containing 4000 doses
Bag of 800 ml solvent	8 ampoules containing 2000 doses
Bag of 800 ml solvent	4 ampoules containing 4000 doses
Bag of 1200 ml solvent	12 ampoules containing 2000 doses
Bag of 1200 ml solvent	6 ampoules containing 4000 doses
Bag of 1600 ml solvent	16 ampoules containing 2000 doses
Bag of 1600 ml solvent	8 ampoules containing 4000 doses

The solvent must be clear, red coloured, without sediment and at room temperature (15–25 °C) at the time of mixing.

2. Preparation of the vaccine shall be planned before the ampoules are taken from the liquid nitrogen and the exact amount of vaccine ampoules and amount of solvent needed shall be calculated first. There is no information available on the number of doses on the ampoules once they are removed from the cane, so special care has to be taken to ensure that the mix-ups of ampoules with different number of doses is avoided and the correct solvent is used.
3. Before withdrawing the ampoules from the liquid nitrogen container, protect hands with gloves, wear long sleeves and use a facemask or goggles. When removing an ampoule from the cane, hold in the palm of a gloved hand away from the body and the face.
4. When withdrawing a cane of ampoules from the canister in the liquid nitrogen container, expose only the ampoule(s) to be used immediately. It is recommended to handle a maximum of 5 ampoules (from one cane only) at a time. After removing the ampoule(s), the remaining ampoules should be put back immediately into the canister in the liquid nitrogen container.
5. Thaw the content of the ampoule(s) rapidly by immersing the ampoule in clean water at 25–27 °C. Gently swirl the ampoule(s) to disperse the contents. In order to protect cells, it is important that the ampoule content is mixed, immediately after thawing, with the solvent. Dry the ampoule, then break the ampoule at its neck and immediately proceed as described below.
6. Gently withdraw the contents of the ampoule into a sterile syringe, fitted with an 18 gauge needle.
7. Insert the needle through the stopper of the solvent bag, and then slowly and gently add the contents of the syringe to the solvent. Gently swirl and invert the bag to mix the vaccine. Withdraw a small quantity from the solvent bag into the syringe and rinse the ampoule. Inject the remaining contents of the ampoule gently into the solvent bag. Remove the syringe and invert the bag (6–8 times) to mix the vaccine.
8. The vaccine is now ready for use.
   After adding the contents of the ampoule to the solvent, the ready to use product is a clear, red coloured suspension for injection.

Control of correct storage:
To allow a check on correct storage and transport the ampoules are placed upside down in the liquid nitrogen containers. If frozen content is situated in the tip of the ampoule, this indicates that the content has been thawed and must not be used.

10. WITHDRAWAL PERIOD(S)

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Cell concentrate: Store and transport frozen in liquid nitrogen (below -140 °C).
Solvent: Store below 30 °C.
Container: Store liquid nitrogen container securely in an upright position in a clean, dry and well-ventilated room separated from the hatching/chicken room.

Shelf life after reconstitution according to directions: 2 hours.

12. SPECIAL WARNING(S)

Special warnings for each target species:
Vaccinate healthy animals only.

Special precautions for use in animals:
As this is a live vaccine, the vaccine strain is excreted from vaccinated birds and may spread to turkeys. Safety 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:
The handling of liquid nitrogen should take place in a well-ventilated area.
Innovax-ND-IBD is a virus suspension packed in glass ampoules and stored in liquid nitrogen. Before withdrawing ampoules from the liquid nitrogen canister, protective equipment consisting of gloves, long sleeves and a facemask or goggles should be worn. In order to prevent serious wounds, by either the liquid nitrogen or the ampoules when removing an ampoule from the canister, hold the palm of (gloved) hand holding the ampoule away from the body and face. Care should be exercised to prevent contaminating the hands, eyes and clothing with the ampoule content. CAUTION: The ampoules have been known to explode on exposure to sudden temperature changes. Do not thaw in hot water or ice-cold water. Thaw the ampoules in clean water at 25–27 °C.

Lay:
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 Innovax-ND-IBD can be mixed in the same solvent and administered by the subcutaneous route with Nobilis Rismavac. For this mixed use, an onset of immunity of 5 days has been demonstrated for MD.

Safety and efficacy data are available which demonstrate that Nobilis ND Clone 30 or Nobilis ND C2 can be administered to day-old chicks that are vaccinated either by the subcutaneous or *in ovo* route with Innovax-ND-IBD. For such associated use, an onset of immunity of 3 weeks (when used with Nobilis ND Clone 30) and 2 weeks (when used with Nobilis ND C2), has been demonstrated for ND.
Safety and efficacy data are available which demonstrate that Nobilis IB Ma5 or Nobilis IB 4-91 can be administered to day-old chicks that are vaccinated either by the subcutaneous or *in ovo* route with the vaccine.

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.

Overdose (symptoms, emergency procedures, antidotes):
No symptoms were observed after the administration of a 10-fold dose of vaccine when applied subcutaneously. A 3-fold overdose was tested *in ovo*, which was regarded as safe. No information is available on the safety or possible adverse reactions following a 10-fold overdose applied *in ovo*.

Incompatibilities:
Do not mix with any other veterinary medicinal product except Nobilis Rismavac and the solvent supplied for use with the veterinary medicinal product.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

{DD/MM/YYYY}

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (http://www.ema.europa.eu/).

15. OTHER INFORMATION

The vaccine is a cell-associated live recombinant turkey herpesvirus (HVT) expressing the F protein of Newcastle disease virus and the VP2 protein of Infectious bursal disease virus. The vaccine induces active immunity against Newcastle disease, infectious bursal disease (Gumboro disease) and Marek's disease in chickens.

Pack sizes:
1 ampoule, containing 2,000 or 4,000 doses. Ampoules are stored on a cane and attached to the cane is a coloured clip displaying the dose (2,000 doses: salmon-pink coloured clip, and 4,000 doses: yellow coloured clip).

Bag of 400 ml solvent, bag of 800 ml solvent, bag of 1200 ml solvent or bag of 1600 ml solvent.

Not all pack sizes may be marketed.