SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINAY MEDICINAL PRODUCT

Nobilis Rismavac

2. QUALITATIVE AND QUANTITATIVE COMPOSITION OF PRODUCT

Active ingredients	**per dose**
Live cell associated Marek's disease virus strain CVI988	≥ 3.0 $\log_{10}$ $TCID_{50}$

Excipients

For a list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Deep frozen suspension for injection after dilution and solvent.

4. CLINICAL PARTICULARS

4.1 Target species

Chickens

4.2 Indications for use specifying the target species

For the vaccination of chickens against Marek's disease.

4.3 Contra-indications

None

4.4 Special warnings for each target species

None

4.5 Special precautions for use

i. Special precautions for use in animals

Only healthy birds should be vaccinated.
The vaccine virus spreads; care should be taken to prevent such spread in multi-age sites.

ii. Special precautions to be taken by the person administering the product to animals

The operator should be aware of the general precautions to be taken when handling liquid nitrogen and/or material at very low temperature. Ampoules may explode on sudden temperature changes; therefore the operator should protect himself with gloves and a visor. When removing an ampoule from a cane hold the palm of a gloved hand away from body and face.
First aid treatment of frost bite injuries: Warm affected part by immersion in water at 29 ± 1 ºC or use body heat. There will be considerable pain during warming, but this is normal. Do not rub affected area, seek medical advice.
After handling vaccine operators should wash and disinfect hands with an approved disinfectant.

4.6 Adverse reactions (frequency and seriousness)

None

4.7 Use during pregnancy, lactation or lay

Not to be used for birds in lay.

4.8 Interaction with other medicinal products and other forms of interaction

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

4.9 Amounts to be administered and administration route

Preparation:
For use the ampoule of vaccine is thawed, by placing in water at room temperature (not hot or icy cold). When the vaccine has thawed the ampoule is opened immediately and diluted in the solvent using a sterile syringe allowing 1000 doses of vaccine to each 200 ml of fluid.

Administration:
Administer by a single injection of 0.2 ml subcutaneously in the neck or intramuscularly in the leg, after reconstitution in the solvent provided. Injection should be made using an approved repeating syringe or automatic vaccinator.
A needle of 20G * ½" should be used to inject the birds.
Equipment used for vaccination should be sterile and contain no traces of detergents or disinfectants.

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

No specific treatment or antidote recommended.

4.11 Withdrawal periods

Zero days

5. PHARMACOLOGICAL PROPERTIES

ATCvet code: QI01AD03

Pharmacotherapeutic group: Immunologicals for Aves, domestic fowl, live viral vaccine.

The vaccine contains live, cell-associated Marek's disease virus for parenteral administration to chickens to stimulate active immunity against the disease.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cell concentrate:
Bovine serum
Veggie medium
Dimethyl sulfoxide

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

6.2 Incompatibilities

Do not mix with any other veterinary medicinal product except Innovax-ILT, Innovax-ND-IBD or Innovax-ND-ILT.

6.3 Shelf life

Vaccine
Shelf life of the cell concentrate as packed for sale: 5 years.
Shelf life after dilution or reconstitution according to directions: 2 hours at +2 °C to +8 °C.

Solvent
Shelf life of the solvent (multilayer plastic bags) as packaged for sale: 3 years.

6.4 Special precautions for storage

Cell concentrate:
Store and transport frozen in liquid nitrogen at a temperature below ≤ -150ºC.
Thawed ampoules must not be refrozen.
Do not expose reconstituted vaccine to direct sunlight or heat.

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: 1,000, 2,000, 4,000 and 5,000 dose ampoules of hydrolytical class type I (Ph. Eur.) glass containing the cell suspension. The ampoules are heat sealed. The ampoules are inserted in metal canes and shipped and stored in a liquid nitrogen container.

Solvent:
- One 200 ml multilayer plastic bag.
- One 400 ml multilayer plastic bag.
- One 500 ml multilayer plastic bag.
- One 600 ml multilayer plastic bag.
- One 800 ml multilayer plastic bag.
- One 1000 ml multilayer plastic bag.
- One 1200 ml multilayer plastic bag.
- One 1600 ml multilayer plastic bag.

Not all presentations may be marketed.

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

Dispose of waste material by boiling, incineration or immersion in an appropriate disinfectant, approved for use by the competent authorities.

7. MARKETING AUTHORISATION HOLDER

Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

8. MARKETING AUTHORISATION NUMBER

Vm 06376/4124

9. DATE OF FIRST AUTHORIATIONS

24 February 1994

10. DATE OF REVISION OF THE TEXT

September 2024

Gavin Hall

Approved: 03 January 2025