SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis Rismavac concentrate and solvent for suspension for injection for chickens

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of the reconstituted vaccine (0.2 ml) contains:

Active substance:
Marek's disease virus, serotype 1, strain CVI988, Live ≥ 3.0 log10 $TCID_{50}$*

*$TCID_{50}$ = Tissue Culture Infective Dose 50%

Excipients:

Qualitative composition of excipients and other constituents
Concentrate:
Bovine serum
Veggie medium
Dimethyl sulfoxide
Solvent:
Sucrose
Sodium chloride
Disodium hydrogen phosphate dihydrate
Phenolsulfonphthalein (Phenol red)
Potassium dihydrogen phosphate
Water for injections

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

3. CLINICAL INFORMATION

3.1 Target species

Chickens.

3.2 Indications for use for each target species

To reduce mortality, clinical signs and lesions after infection with Marek's disease virus (MDV).
For the vaccination of one-day old chickens against Marek's disease.

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:

The vaccine virus spreads; care should be taken to prevent such spread in multi-age sites.
A good immune response is reliant on the reaction of an immunogenic agent and a fully competent immune system. Immunogenicity of the vaccine antigen will be reduced by poor storage or inappropriate administration.
Immunocompetence of the animal may be compromised by a variety of factors including poor health, nutritional status, genetic factors, concurrent drug therapy and stress.
Under certain conditions, for example extreme disease pressure and variant challenge, fully immune birds may succumb to disease. Therefore, successful vaccination may not be synonymous with full protection in the face of a disease challenge.

Special precautions to be taken by the person administering the veterinary medicinal 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 °C ± 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.

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 °C – 27 °C.

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

Laying birds:

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 in the same solvent and administered by the subcutaneous route 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. The product information of the other product should also be consulted in case of mixed use.

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.

3.9 Administration routes and dosage

Subcutaneous or intramuscular use.

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 1 000 doses of vaccine to each 200 ml of fluid.

Administration:
The recommended age for vaccination is day-old.
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 x ½” should be used to inject the birds.
Equipment used for vaccination should be sterile and contain no traces of detergents or disinfectants.

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

Following the administration of a 10-fold dose, no adverse events other than those described in section 3.6 have been observed.

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.

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

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product except Innovax-ILT, Innovax-ND-IBD or Innovax-ND-ILT and the solvent supplied for use with the veterinary medicinal product.

5.2 Shelf life

Shelf life of the cell concentrate as packed for sale: 5 years.
Shelf life after reconstitution according to directions: 2 hours.

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

5.3 Special precautions for storage

Concentrate:
Store and transport frozen in liquid nitrogen at a temperature below ≤ -150 °C.
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.

5.4 Nature and composition of immediate packaging

Concentrate: 1 000, 2 000, 4 000 and 5 000 dose ampoules of hydrolytic 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 multilayer plastic bag of 200 ml, 400 ml, 500 ml, 600 ml, 800 ml, 1 000 ml, 1 200 ml or 1 600 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

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

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

Intervet International B.V.

7. MARKETING AUTHORISATION NUMBER

Vm 06376/4124

8. DATE OF FIRST AUTHORISATION

24 February 1994

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

September 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the ‘Product Information Database’ on www.gov.uk.

Approved 23 December 2025

Gavin Hall