

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING
UNITS**

Label for the vaccine ampoule (Glass ampoule for the concentrate, 2 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis Rismavac

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

CVI988

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

PARTICULARS TO APPEAR ON THE IMMEDIATE LABEL OF THE SOLVENT
(solvent bag)

1. NAME OF THE DILUENT/SOLVENT

Solvent for cell associated poultry vaccines.

200 ml
400 ml
500 ml
600 ml
800 ml
1000 ml
1200 ml
1600 ml

2. TARGET SPECIES

3. ROUTE(S) OF ADMINISTRATION

Read package leaflet before use.

4. EXPIRY DATE

EXP. {MM /YYYY}

5. SPECIAL STORAGE PRECAUTIONS

Store below 30 °C.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.

7. BATCH NUMBER

Lot {number}

For animal treatment only.

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Nobilis Rismavac concentrate and solvent for suspension for injection for chickens

2. Composition

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

Active substance:

Marek's disease virus, serotype 1, strain CVI988, Live $\geq 3.0 \log_{10} \text{TCID}_{50}^*$

*TCID₅₀ = Tissue Culture Infective Dose 50%

Concentrate: off-red to red cell concentrate.

Solvent: clear, red solution.

3. Target species

Chickens.

4. Indications for use

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.

5. Contraindications

None.

6. Special warnings

Special warnings:

Vaccinate healthy animals only.

Special precautions for safe use in the target species:

The vaccine viruses spread; 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. After handling vaccine operators should wash and disinfect hands with an approved disinfectant.

First aid treatment of frost bite injuries: Warm affected part by immersion in water at $29\text{ }^{\circ}\text{C} \pm 1\text{ }^{\circ}\text{C}$ or use body heat. There will be considerable pain during warming, but this is normal. Do not rub affected area, seek medical advice. 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 $25\text{ }^{\circ}\text{C} - 27\text{ }^{\circ}\text{C}$.

Laying birds:

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 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.

Overdose:

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

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.

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 at:

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: adverse.events@vmd.gov.uk

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

Subcutaneous or intramuscular use.

Day old chicks

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 20 g x 1/2" should be used to inject the birds. Equipment used for vaccination should be sterile and contain no traces of detergents or disinfectants. The recommended age for vaccination is day-old.

Number of doses per ampoule	Volume of solvent per ampoule needed for reconstitution of the vaccine
	SC / IM (0.2 ml per dose)
1 000 doses	200 ml
2 000 doses	400 ml
4 000 doses	800 ml
5 000 doses	1 000 ml

9. Advice on correct administration

Reconstitution:

The actual volume of solvent per dose needed for reconstitution of the vaccine may depend on the number of doses per ampoule, the route of administration on the settings of the vaccination equipment. In the table above the volume of solvent per ampoule for the various dose-presentations, routes of administration are given. Prior to reconstitution the vaccine is thawed. Great care should be taken – see section ‘special precautions to be taken by the person administering the veterinary medicinal product to animals’. Remove one ampoule from the cane and immediately replace the cane in the liquid nitrogen canister. Thaw the contents of the ampoule rapidly by immersing in water at room temperature. Do not thaw in hot or ice-cold water. Dry the ampoule and shake to disperse contents. After thawing open the ampoule immediately and draw the entire contents into a sterile 5 – 10 ml syringe using an 18-gauge needle to avoid rupturing the cells. Insert the needle through the stopper of the solvent vial (which should be at room temperature) and draw up slowly a portion of the diluent. Add the contents of the syringe to the remaining solvent. It is

important that this is done slowly, allowing the vaccine to run down the side of the bottle. Gently shake the bottle as the vaccine is being mixed. Withdraw a portion of the vaccine and use to rinse the ampoule. Inject the washing back into the solvent vial. The reconstituted vaccine must be handled gently and administered through wide gauge needles to avoid rupturing the cells. Fill the sterilised repeating syringe / automatic vaccinator according to the manufacturer's instructions. The vial of reconstituted vaccine should be kept in an ice bath when not being used.

10. Withdrawal periods

Zero days.

11. Special storage precautions

Keep out of the sight and reach of children.

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.

Shelf life after reconstitution according to directions: 2 hours.

Do not use this veterinary medicinal product after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

12. Special precautions for disposal

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 applicable 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

Vm 06376/4124

Pack sizes:

Concentrate: One Type I glass ampoule of 2 ml containing 1000, 2000, 4000 or 5000 doses. Ampoules are stored on a cane.

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

Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

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

16. Contact details

Marketing authorisation holder:

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

Manufacturer responsible for batch release:

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

Local representative:

MSD Animal Health UK Limited.
Walton Manor, Walton
Milton Keynes, MK7 7AJ, United Kingdom

Contact details to report suspected adverse reactions:

UK(GB)

MSD Animal Health UK Ltd.
Tel.: +44 (0)1908 685685

UK(NI)

Intervet Ireland Ltd.
Tel.: +353 (0)1 2970220

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information

The vaccine is supplied in separate units. One consists of the deep-frozen ampoules containing the cell associated vaccine viruses and the other consists of bottles or infusion bags with sterile diluent.

The ampoules are inserted in metal cases and shipped in a liquid nitrogen container.

POM- VPS

Approved 23 December 2025

Gavin Hall