SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis Rismavac + CA126 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 substances:

Turkey herpesvirus, strain FC-126 (cell-associated), Live ≥ 3.0 $\log_{10}$ pfu*
Marek's disease virus, serotype 1, strain CVI-988 (Rispens, cell-associated), Live ≥ 3.0 $\log_{10}$ pfu*

*pfu: plaque forming units

Excipients:

Qualitative composition of excipients and other constituents
Concentrate:
Bovine serum
Veggie medium
Dimethyl sulfoxide
Solvent:
Sucrose
Sodium chloride
Disodium hydrogen phosphate dihydrate
Phenolsulfonphtalein (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

For the active immunisation of chickens to reduce mortality, clinical signs and lesions after infection with Marek's disease virus.

Nobilis Rismavac + CA126 may be used for vaccination of day-old chicks and for *in-ovo* vaccination of 18 day embryonated eggs.

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 presence of maternal antibodies to Marek's can affect the efficacy of the vaccine. 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.

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 thermal 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 °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.

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. Do not use in birds in lay and within 4 weeks before the start of the laying period.

3.8 Interaction with other medicinal products and other forms of interaction

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.
There is evidence that some antibiotics may interfere with the performance of Marek's vaccines if mixed for administration.

3.9 Administration routes and dosage

Day-old vaccination:
Subcutaneous or intramuscular use.
Inject 0.2 ml reconstituted vaccine to each bird subcutaneously in the neck or intramuscularly in the leg using a 20g x 1/2" needle with an approved repeating syringe or automatic vaccinator.
Equipment used for vaccination should be sterile and contain no traces of detergents or disinfectants.

In ovo vaccination:
In ovo use.
Inject one dose of the reconstituted vaccine to each 18-day embryonated egg with an appropriate automatic *in ovo* vaccinator. The actual volume per dose may depend on the settings of the *in ovo* vaccination equipment. This should not be less than 50 µl or more than 100 µl. Depending on the volume to be administered the vaccine should be reconstituted according to the instructions below. The egg should be in an upright position with the blunt side up.

***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 and for *in ovo* on the settings of the vaccination equipment. In the table below the volume of solvent per ampoule for the various dose-presentations, routes of administration and settings of the *in ovo* equipment are given.

	Volume of solvent per ampoule needed for reconstitution of the vaccine		
Number of doses per ampoule	sc / im (0.2 ml per dose)	*in ovo* (0.05 ml per dose)	*in ovo* (0.1 ml per dose)
1000 doses	200 ml	50 ml	100 ml
2000 doses	400 ml	100 ml	200 ml
4000 doses	800 ml	200 ml	400 ml
5000 doses	1000 ml	250 ml	500 ml

After adding the contents of the ampoule to the solvent, the ready to use product is a clear, red coloured suspension for injection.

Prior to reconstitution the vaccine is thawed. Great care should be taken - see 3.5 Special precautions for use. 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 solvent. 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 in to 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.

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. Occasional microscopic lesions might be seen after in ovo vaccination. No specific treatment or antidote recommended.

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.

Vaccine contains cell associated live Turkey and Chicken Herpes viruses to stimulate 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 the solvent recommended for use with the veterinary medicinal product.

5.2 Shelf life

Vaccine
Shelf life of the concentrate as packaged for sale: 4 years.
Shelf life after reconstitution according to directions: 2 hours when kept at +2°C to +8°C.

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

5.3 Special precautions for storage

Concentrate:
Store in liquid nitrogen at a temperature below ≤ -150 ºC.
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: 1000, 2000, 4000 and 5000 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, 1000 ml, 1200 ml or 1600 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 06376/4125

8. DATE OF FIRST AUTHORISATION

13 November 1997

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

December 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.

Gavin Hall

Approved: 26 March 2026