

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF VETERINARY MEDICINAL PRODUCT

Nobilis Rismavac + CA126

2. QUALITATIVE AND QUANTITATIVE COMPOSITION OF PRODUCT

Active ingredients	per dose
Live Turkey Herpes virus strain FC126	$\geq 3.0 \log_{10}$ PFU
Live Chicken Herpes virus strain CVI-988	$\geq 3.0 \log_{10}$ PFU

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

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

4.3 Contra-indications

None

4.4 Special warnings for each target species

None

4.5 Special precautions for use

i. Special precautions of the use in animals

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.

- ii. Special precautions to be taken by 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 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 $29 \pm 1^{\circ}\text{C}$ or use body heat. There will be considerable pain during warming, but this is normal. Do not rub affected area, seek medical advice.

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 Interactions 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 interference with the performance of Marek's vaccines if mixed for administration.

4.9 Amounts to be administered and administration route

Day-old vaccination:

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.

In-ovo vaccination:

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 50µl or more than 100µl. 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.

Number of doses per ampoule	Volume of solvent per ampoule needed for reconstitution of the vaccine		
	sc / im (0.2 ml per dose)	<i>in-ovo</i> (0.05 ml per dose)	<i>in-ovo</i> (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

Prior to reconstitution the vaccine is thawed. Great care should be taken - see operator warnings. 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.

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

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

4.11 Withdrawal periods

Zero days

5. IMMUNOLOGICAL PROPERTIES

ATC Vet Code: QI01AD03

Pharmacotherapeutic group: Immunologicals for aves, Domestic fowl, Live viral vaccines

Vaccine contains cell associated live Turkey and Chicken Herpes viruses to stimulate active immunity against Marek's disease in chickens.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Vaccine

Calf serum

DMSO

Solvent

Sucrose

Pancreatic digest of casein

Potassium dihydrogen phosphate

Phenolsulfonphthalein

Water for injections

6.2 Major incompatibilities

Do not mix with other veterinary medicinal products.

6.3 Shelf life

Vaccine

Shelf life of the veterinary medicinal product as packaged for sale: 4 years

Shelf life after dilution or reconstitution according to directions:

2 hours when kept at +2°C to +8°C.

Solvent

Shelf life as packaged for sale: 3 years in glass bottles or polyethylene bags
2 years in multilayer plastic bags

6.4 Storage precautions

Store in liquid nitrogen at a temperature below $\leq -150^{\circ}\text{C}$

Thawed ampoules must not be refrozen.

Do not expose reconstituted vaccine to direct sunlight or heat.

6.5 Nature and composition of immediate packaging

Vaccines

1000, 2000, 4000 and 5000 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

200, 400 and 500 ml in type II glass vials closed with a halogenobutyl rubber stopper and an aluminium crimp cap.

200, 400, 500, 600, 800, 1000, 1200 ml in polyethylene bags

200, 400, 500, 600, 800, 1000 ml in multilayer plastic bags

Not all presentations may be marketed.

6.6 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

MSD Animal Health UK Limited
Walton Manor
Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

8. MARKETING AUTHORISATION NUMBER

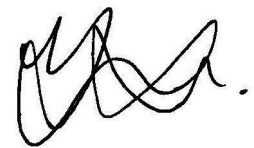
Vm 01708/4354

9. DATE OF FIRST AUTHORISATION

13 November 1997

10. DATE OF REVISION OF THE TEXT

July 2020



Approved: 03 July 2020