Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis Rismavac + CA126

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance	**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 full list of excipients, see section 6.1

* pfu = plaque forming units in chicken embryo fibroblasts

3 PHARMACEUTICAL FORM

Concentrate for solution for injection.

4 CLINICAL PARTICULARS

4.1 Target Species

Chickens

4.2 Indications for use, specifying the target species

For the active immunisation of 18-day embryonated eggs or day-old chickens to reduce mortality, clinical signs and lesions after infection with Marek's Disease virus.
Duration of immunity is unknown.

4.3 Contraindications

None

4.4 Special warnings for each target species

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. Immuno-competence 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, fully immune birds may succumb to disease. Therefore, successful vaccination may not be synonymous with full protection in the face of a disease challenge.

4.5 Special precautions for use

Special precautions for use in animals
Do not use in unhealthy birds. Sick or weak birds will not develop adequate immunity following vaccination.
The vaccine viruses spread; care should be taken to prevent such spread in multi-age sites.

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 $\pm$ 1ºC 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 or within 4 weeks before the onset of the laying period.

4.8 Interaction with other medicinal products and other forms of interaction

No information is available on the safety and efficacy of concurrent use of this vaccine with any other. It is therefore recommended that no other vaccine should be administered within at least 7 days of vaccination with the product.

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 0.05 – 0.1 ml to each 18-day embryonated egg. The actual volume per dose will depend on the settings of the *in ovo* vaccination equipment.

Reconstitution:

Number of dose per vial (1.8 ml fill)	Volume of diluent (ml) for IM/SC	Volume of diluent (ml) for in-ovo
1000	200	50 - 100
2000	400	100 - 200
4000	800	200 - 400
5000	1000	250 - 500

Reconstitute the vaccine in Nobilis Diluent CA, allowing 200 ml diluent per 1000 doses for i.m or s.c. vaccination, and 50 – 100 ml per 1000 doses for *in ovo* vaccination.

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 or port of the diluent vial or bag (which should be at room temperature) and slowly draw up a portion of the diluent. Add the contents of the syringe to the remaining diluent. It is important that this is done slowly, allowing the vaccine to run down the side of the bottle or bag. Gently shake the bottle or bag 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 diluent vial or bag. If necessary multiple vaccine ampoules can be diluted in one diluent vial or bag containing the appropriate volume for the amount of vaccine.

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 or bag 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.

4.11 Withdrawal Period(s)

Zero days

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

QI01AD03
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: Dimethylsulfoxide (DMSO)
Bovine serum
Diluent: Sucrose
Pancreatic digest of casein
Potassium dihydrogen phosphate
Phenolsulphonphthalein
Water for injections

6.2 Incompatibilities

Do not mix with any other medicinal product except for the diluent supplied for use with this vaccine.

6.3 Shelf-life

Shelf-life of the vaccine as packaged for sale: 3 years

Shelf-life of the diluent as packaged for sale:
Glass vials and polyethylene bags: 3 years
Multilayer plastic bags: 2 years

Shelf-life after dilution: 2 hours

6.4 Special precautions for storage

Vaccine: Store in liquid nitrogen below -150°C.
Thawed ampoules must not be refrozen.
Solvent: Store below 25°C. Do not freeze. Protect from light.
Once diluted store in a refrigerator (2°C -8°C)

6.5 Nature and composition of immediate packaging

Vaccine:
Flame sealed 2 ml ampoules of hydrolytic quality type I glass containing the cell suspension as 1000, 2000, 4000 or 5000 doses. The ampoules are inserted in metal canes and shipped and stored in a liquid nitrogen container.
Diluent:
Bottles of hydrolytic type II glass, closed with rubber stoppers and sealed with an aluminium cap, containing 200 ml, 400 ml and 500 ml.
Polyethylene bags closed with rubber stoppers and sealed with an aluminium cap, containing 200 ml, 400 ml, 500ml, 600ml, 800 ml, 1000ml and 1200ml.
Multilayer plastic (MLP) bags with a port system containing 200 ml, 400 ml, 500 ml, 600 ml, 800 ml and 1,000 ml.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Dispose of waste material by boiling, incineration or immersion in an appropriate disinfectant in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

Intervet Ireland Ltd.
Magna Drive
Magna Business Park
Citywest Road
Dublin 24

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10996/086/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

5th August 2008

10 DATE OF REVISION OF THE TEXT

May 2017