ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Label for the tube of ampoules

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis Marexine CA126
Suspension for injection

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Per dose:
≥10^3 pfu Marek's Disease Virus (strain FC126)

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

2000 doses

4. ROUTE(S) OF ADMINISTRATION

Route: IM or SC injection in chickens.

5. WITHDRAWAL PERIOD(S)

Withdrawal period(s): Zero days.

6. BATCH NUMBER

Batch no: {number}

7. EXPIRY DATE

EXP end of: {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

Keep out of the sight and reach of children.
Read insert card before use.

MA Holder:
MSD Animal Health UK Ltd
Walton Manor
Walton
Milton Keynes
MK7 7AJ

POM-VPS
To be supplied only on veterinary prescription.

Vm 01708/4289

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

Label for the solvent

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Solvent for cell associated poultry vaccines.
Read package leaflet before use. Store below 25 °C.

2. NAME OF THE MARKETING AUTHORISATION HOLDER

MA Holder:
MSD Animal Health UK Ltd
Walton Manor
Walton
Milton Keynes
MK7 7AJ

3. EXPIRY DATE

EXP: {month/year}

4. BATCH NUMBER

Lot: {number}

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

Label for the vaccine

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis Marexine CA 126
Marek vaccine, FC 126 (HVT) ≥1000 pfu/dose.

2. NAME OF THE MARKETING AUTHORISATION HOLDER

MA Holder:
MSD Animal Health UK Ltd
Walton Manor
Walton
Milton Keynes
MK7 7AJ

3. EXPIRY DATE

EXP: {month/year}

4. BATCH NUMBER

Batch: {number}

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

Inj. I.M./S.C.
Animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

Nobilis Rismavac, Nobilis Rismavac CA126, Nobilis Marexine CA126

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
MSD Animal Health UK Ltd
Walton Manor
Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

Manufacturer responsible for batch release:
Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis® Rismavac
Nobilis® Rismavac + CA 126
Nobilis® Marexine CA 126
(Cell associated Marek's vaccines)
Suspension for injection for chickens.

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Nobilis® Rismavac:
One dose contains
Live cell associated Marek's disease virus strain CVI988 3.0 $\log_{10}$ $TCID_{50}$
Nobilis® Marexine CA 126:
One dose contains
Live Turkey Herpes virus strain FC126 3.0 $\log_{10}$ PFU
Nobilis® Rismavac + CA 126:
One dose contains
Live Turkey Herpes virus strain FC126 3.0 $\log_{10}$ PFU
Live Chicken Herpes virus strain CVI-988 > 3.0 $\log_{10}$ PFU
Solvent:
Sterile buffer solution containing:
Sucrose, Pancreatic digest of casein, Monobasic potassium phosphate, Phenolsulphonphthalein, Water for injections.
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.

4. INDICATION(S)

To reduce mortality, clinical signs and lesions after infection with Marek's disease virus (MDV).
Nobilis Rismavac and Nobilis Marexine CA 126 may be used for vaccination of day-old chicks.
Nobilis Rismavac + CA 126 may be used for vaccination of day-old chicks and for in-ovo vaccination of 18 day embryonated eggs.

5. CONTRAINDICATIONS

Only healthy birds should be vaccinated.
Do not use in birds in lay.

6. ADVERSE REACTIONS

Occasional microscopic lesions might be seen after in-ovo vaccination.
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Chickens.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Day old chicks
Nobilis Marexine CA 126 or Nobilis Rismavac or Nobilis Rismavac + CA 126
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.
In-ovo vaccination
Nobilis Rismavac + CA 126 only
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 that 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.

Number of doses per ampoule	Volume of solvent per ampoule needed for reconstitution of the vaccine		
	SC / IM (0.2 ml per dose)	in-ovo (Rismavac + CA 126 only) (0.05 ml per dose)	in-ovo (Rismavac + CA 126 only) (0.1 ml per dose)
1000 doses	200 ml	50 ml	1000 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

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 and for in-ovo 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 and settings of the in-ovo equipment are given.
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 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 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.

10. WITHDRAWAL PERIOD(S)

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store and transport frozen in liquid nitrogen at a temperature below -150 °C.
Thawed ampoules must not be refrozen.
Once diluted the vaccine should be kept at 2° to 8 °C and used within 2 hours.
Do not expose reconstituted vaccine to direct sunlight or heat.
Solvent: Store below 25 ºC.
Do not use after the expiry date stated on the outer label.

12. SPECIAL WARNING(S)

The presence of antibodies to Marek's can affect the efficacy of vaccination.
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.

Interactions

Nobilis Marexine CA126 and Nobilis Rismavac:
Nobilis Rismavac and Nobilis Marexine CA126 which can be co-administered (if the combination vaccine Nobilis Rismavac+CA126 is unavailable).
Nobilis Rismavac + CA 126:
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.
Do not mix with any other veterinary medicinal products.
There is evidence that some antibiotics may interference with the performance of Marek's vaccines if mixed for administration.

Operator warning

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° ± 1 °C or use body heat. There will be considerable pain during warming, but this is normal. Do not rub affected area, seek medical advice.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

December 2020.

15. OTHER INFORMATION

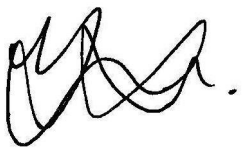
For animal treatment only.

Legal category
POM-VPS
To be supplied only on veterinary prescription.

Package quantities
Vaccine: Ampoules containing 1000, 2000, 4000 or 5000 doses.
solvent: bottles or infusion bags containing 200, 400, 500, 600, 800, 1000 or 1200 ml.
Not all presentation may be marketed.

Marketing authorisation numbers
Vm 01708/4289 Nobilis Marexine CA 126.
Vm 01708/4294 Nobilis Rismavac.
Vm 01708/4354 Nobilis Rismavac+CA126.

Distributor in Northern Ireland:
Intervet Ireland Ltd.
Magna Drive
Magna Business Park
Citywest Road
Dublin 24



Approved: 02 December 2020