

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**Plastic box**

**Labelling information on inlay cover, front label and back label seals**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Nobivac Rabies Suspension for injection

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

Each 1 ml dose contains:

Inactivated rabies virus, strain Pasteur RIV:  $\geq 2$  IU

Aluminium phosphate (adjuvant): 0.60 - 0.88 mg Al<sup>3+</sup>

Thiomersal (preservative): 0.1 mg

**3. PHARMACEUTICAL FORM**

Suspension for injection

**4. PACKAGE SIZE**

10 x 1 ml

50 x 1 ml

**5. TARGET SPECIES**

Dogs and cats.

**6. INDICATION(S)**

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

Intramuscular or subcutaneous use.

**Read package leaflet before use.**

**8. WITHDRAWAL PERIOD**

Not applicable.

**9. SPECIAL WARNING(S), IF NECESSARY**

**SECTIONS 10 – 17 ARE PRINTED ON THE FRONT AND BACK SEAL LABELS**

**10. EXPIRY DATE**

EXP: {month/year}

**11. SPECIAL STORAGE CONDITIONS**

Store in a refrigerator.  
Do not freeze.  
Protect from light.

Keep the vials in the outer box.

**12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY**

Read package leaflet before use.

**13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE**

For animal treatment only.

POM-V

To be supplied only on veterinary prescription.

**14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”**

Keep out of the sight and reach of children.

**15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

**MA holder**  
MSD Animal Health UK Ltd.  
Walton Manor, Walton  
Milton Keynes  
MK7 7AJ

**Distributor in Northern Ireland**

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

**16. MARKETING AUTHORISATION NUMBER(S)**

Vm 01708/4325

**17. MANUFACTURER'S BATCH NUMBER**

Lot: {number}

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

Cardboard box

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Nobivac Rabies Suspension for injection

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

Each 1 ml dose contains:

Inactivated rabies virus, strain Pasteur RIV:  $\geq 2$  IU

Aluminium phosphate (adjuvant): 0.60 - 0.88 mg Al<sup>3+</sup>

Thiomersal (preservative): 0.1 mg

**3. PHARMACEUTICAL FORM**

Suspension for injection

**4. PACKAGE SIZE**

1 x 1 ml

10 x 1 ml

50 x 1 ml

**5. TARGET SPECIES**

Dogs and cats.

**6. INDICATION(S)**

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

Intramuscular or subcutaneous use.

**Read package leaflet before use.**

1 x 1 ml presentation only:

IM or SC use.

**8. WITHDRAWAL PERIOD**

Not applicable.

**9. SPECIAL WARNING(S), IF NECESSARY**

**10. EXPIRY DATE**

EXP: {month/year}

**11. SPECIAL STORAGE CONDITIONS**

Store in a refrigerator.  
Do not freeze.  
Protect from light.

Keep the vial(s) in the outer box.

**12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY**

Disposal: read package leaflet.

**13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE**

For animal treatment only.

To be supplied only on veterinary prescription.

POM-V

**14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”**

Keep out of the sight and reach of children.

**15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

**MA holder**  
MSD Animal Health UK Ltd.  
Walton Manor, Walton  
Milton Keynes  
MK7 7AJ

**Distributor in Northern Ireland**

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

**16. MARKETING AUTHORISATION NUMBER(S)**

Vm 01708/4325

**17. MANUFACTURER'S BATCH NUMBER**

Lot: {number}

Carton of the 1 x 1 ml cardboard box presentation only:

**NZ only:** RVM.

ACVM No. A009450.

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

**Vaccine vial label**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Nobivac Rabies

**2. QUANTITY OF THE ACTIVE SUBSTANCE(S)**

Inactivated rabies virus:  $\geq 2$  IU/ml

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

1 ml

**4. ROUTE(S) OF ADMINISTRATION**

IM or SC use.

**5. WITHDRAWAL PERIOD**

Not applicable.

**6. BATCH NUMBER**

Lot: {number}

**7. EXPIRY DATE**

EXP: {month/year}

**8. THE WORDS "FOR ANIMAL TREATMENT ONLY"**

For animal treatment only.

Keep the vial(s) in the outer box.

**UK only:** POM-V Vm 01708/4325

Label of the 1 x 1 ml cardboard box presentation only:

**NZ only:** RVM.

ACVM No. A009450.



**PACKAGE LEAFLET FOR:  
Nobivac Rabies Suspension for injection**

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

**2. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Nobivac Rabies Suspension for injection

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

Each 1 ml dose contains:

**Active substance:**

Inactivated rabies virus strain Pasteur RIV:  $\geq 0.95$  AIU\* equivalent to 2 IU\*\*

\* Batch control is performed with an *in vitro* potency test according to Ph. Eur. monograph 451. AIU = rabies antigenic mass AlphaLISA International Units.

\*\* Corresponding potency in the *in vivo* mouse challenge test according to Ph. Eur. monograph 451.

**Adjuvant:**

Aluminium phosphate (adjuvant): 0.60 - 0.88 mg Al<sup>3+</sup>

**Excipients:**

Thiomersal (preservative): 0.1 mg

Light yellow/orange to slightly red/purple with a whitish sediment.

**4. INDICATION(S)**

For the active immunisation against rabies to reduce clinical signs and mortality.

Onset of immunity: an adequate serological response ( $\geq 0.5$  IU) has been demonstrated 2 to 3 weeks after vaccination.

Duration of immunity: 3 years.

## 5. CONTRAINDICATIONS

None.

## 6. ADVERSE REACTIONS

Transient local reactions such as non-painful diffuse to firm swellings of approximately 1 cm in diameter may be observed for up to 3 weeks after subcutaneous vaccination.

A transient acute hypersensitivity reaction - with signs that may include, facial oedema, vomiting, pruritus or diarrhoea - may occur shortly after vaccination in very rare cases. Such reactions may evolve to a more severe condition (anaphylaxis), which may be life-threatening with additional signs like dyspnoea, collapse, ataxia, muscle tremor and convulsion. If such reactions occur appropriate treatment is recommended.

Clinical signs of immune-mediated haemolytic anaemia, immune-mediated thrombocytopenia or immune-mediated polyarthritis have been reported in very rare cases.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

## 7. TARGET SPECIES

Dogs and cats.

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

Administer a dose of 1 ml irrespective of the size, species or breed of animal. Intramuscular or subcutaneous use.

Primary course and booster vaccinations:

Primary vaccination age\*: 12 weeks or older

Booster vaccination every: 3 years

\*The primary vaccination may be administered at an earlier age, but a second dose must then be administered at the age of 12 weeks.

Minimum vaccination age in dogs and cats: 4 weeks.

Further information:

Limited safety data are available for ferrets from monitoring post vaccination reactions.

Ferrets can be vaccinated subcutaneously from 12 weeks of age. An adequate serological response ( $\geq 0.5$  IU) has been demonstrated 1 month after vaccination. Ferrets should receive a booster vaccination every 18 months.

## **9. ADVICE ON CORRECT ADMINISTRATION**

Sterile equipment should be used for administration.

Avoid contamination of vaccine with traces of chemical sterilising agents. Do not use chemicals such as disinfectant or spirit to disinfect the skin prior to inoculation.

## **10. WITHDRAWAL PERIOD(S)**

Not applicable.

## **11. SPECIAL STORAGE PRECAUTIONS**

Keep out of the sight and reach of children.

Store in a refrigerator (2 °C to 8 °C).

Do not freeze.

Protect from light.

Keep the vial(s) in the outer box.

Do not use after the expiry date stated on the label and outer box after 'EXP'. The expiry date refers to the last day of that month.

## **12. SPECIAL WARNING(S)**

Special warnings for each target species:

Vaccinate healthy animals only.

The vaccine may not be effective in animals incubating the disease at the time of vaccination.

Some animals may be immunologically incompetent and fail to respond to vaccination. A good immune response is reliant on the reaction of an immunogenic agent and a fully competent immune system. 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 for use in animals:

The presence of maternal antibodies can interfere with the response to vaccination.

Nobivac Rabies should not be administered for at least one month following the administration of hyperimmune serum (anti-serum) or immunosuppressant drugs.

Immunogenicity of the vaccine antigen will be reduced by poor storage or inappropriate administration.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Pregnancy:

Can be used during pregnancy in dogs. There are no laboratory data on use during pregnancy in other species, but on basis of field experience, such use is expected to be safe.

Interactions with other medicinal products and other forms of interaction:

Safety and efficacy data are available which demonstrate that Nobivac Rabies can be mixed and administered with vaccines in the Nobivac range containing one or more of the following components: live canine distemper, canine adenovirus, canine parvovirus and canine parainfluenza or live feline viral rhinotracheitis virus, feline calicivirus and feline panleucopenia virus.

Safety and efficacy data are available which demonstrate that Nobivac Rabies can be administered on the same day but not mixed with Nobivac vaccines containing canine *Leptospira interrogans* serogroups Canicola and Icterohaemorrhagiae antigens.

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 (symptoms, emergency procedures, antidotes):

No effects other than those mentioned in section 6.

Incompatibilities:

Do not mix with any other veterinary medicinal products except components recommended for use with the veterinary medicinal product listed above in section 12.

**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 product should be disposed of in accordance with local requirements.

**14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED**

December 2021

## 15. OTHER INFORMATION

For animal treatment only.

### Pet Travel Scheme (PETS)

Animals intended for vaccination under the Pet Travel Scheme (PETS) must be identified by a permanent numbered microchip. This microchip number must be recorded on the pet passport/vaccination record of the animal at the time of rabies vaccination.

Health regulations and requirements in certain countries specify that animals must be revaccinated annually against rabies.

Prior to any international travel with pets, or travel to and from Northern Ireland, always check rabies vaccination requirements of destination countries well in advance of the planned departure dates.

ATCvet code: QI07AA02

The vaccine contains inactivated antigens to stimulate active immunity against rabies.

### Pack sizes:

Cardboard box with 1 x 1 ml vial

Cardboard or plastic (PET) box with 10 x 1 ml or 50 x 1 ml vials

Not all pack sizes may be marketed.

**MA number:** Vm 01708/4325

**POM-V**

To be supplied only on veterinary prescription.

### **Distributor in Northern Ireland**

Intervet Ireland Ltd.

Magna Drive, Magna Business Park

Citywest Road, Dublin 24

Package leaflet of 1 x 1 ml cardboard box presentation only:

#### **NZ only**

RESTRICTED VETERINARY MEDICINE

Registered pursuant to the ACVM Act 1997, No. A009450.

See [www.foodsafety.govt.nz](http://www.foodsafety.govt.nz) for registration conditions.

Approved: 23/12/21

