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: ≥ 2 IU
Aluminium phosphate (adjuvant): 0.60 - 0.88 mg Al^{3+}
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
Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
Netherlands

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 06376/4106

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: ≥ 2 IU
Aluminium phosphate (adjuvant): 0.60 - 0.88 mg Al^{3+}
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
Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
Netherlands

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 06376/4106

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: ≥ 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 06376/4106

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
Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
Netherlands

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: ≥ 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^{3+}

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 (≥ 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.

<u>Primary course and booster vaccinations:</u>
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 (≥ 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. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the ‘Product Information Database’ on www.gov.uk.

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 06376/4106

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 for registration conditions.

Gavin Hall

Approved: 19 December 2024