1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac Rabies suspension for injection for dogs and cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

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 2 % 0.15 ml

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Maintenance medium	
Disodium hydrogen phosphate dihydrate	
Sodium dihydrogen phosphate dihydrate	
Thiomersal	0.10 mg
Water for injections	

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

3. CLINICAL INFORMATION

3.1 Target species

Dogs and cats.

3.2 Indications for use for each target species

For the active immunisation of dogs and cats to reduce mortality and clinical signs of rabies.

Onset of immunity: 30 days.
Duration of immunity: 3 years.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

3.5 Special precautions for use

Special precautions for safe use in the 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. Immunocompetence of the animal may be compromised by a variety of factors including poor health, nutritional status, genetic factors, concurrent drug therapy and stress. The vaccine may not be effective in animals incubating the disease at the time of vaccination.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In the case of accidental self-injection, wash the area immediately with water. If symptoms develop, seek medical advice and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Dogs and cats:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Injection site reactions[1]. Hypersensitivity reaction[2]. Lethargy, Anorexia, Hyperthermia.

[1] Diffuse to firm swellings (1 to 4 cm in diameter) may be observed for up to 3 weeks after subcutaneous vaccination. Swelling may be painful for up to 3 days post administration.
[2] Reaction may evolve to a more severe condition (anaphylaxis), which may be life-threatening.. If such reaction occurs, appropriate treatment by the most immediate route is recommended (i.e. antihistamines corticosteroids or adrenaline).

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:
Can be used during pregnancy.

3.8 Interaction with other medicinal products and other forms of interaction

Safety and/or efficacy data are available which demonstrates that this vaccine can be mixed with single or multi-component vaccines of the Nobivac range containing only the following live viral antigens: canine distemper virus (strain Onderstepoort), canine adenovirus (strain Manhattan LPV3), canine parvovirus (strain 154) or canine parainfluenza virus (strain Cornell).

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 decided on a case by case basis.

3.9 Administration routes and dosage

Intramuscular or subcutaneous use.

Administer one dose (1 ml).

Allow the vaccine to reach room temperature (15 °C – 25 °C) temperature before use.
Shake before use.

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.

Vaccination programme
Primary vaccination
Animals less than 12 weeks of age:
If born to unvaccinated dams: Primary vaccination may be administered from 4 weeks of age.
If born to vaccinated dams: Maternally derived antibodies could interfere with the response to vaccination. Puppies and kittens born to dams vaccinated against rabies should be vaccinated from 12 weeks of age, or if vaccinated before this age, a second dose should be administered at 12 weeks of age.

Older animals:
Primary vaccination may be administered from 12 weeks of age.

Revaccination
To maintain immunity, dogs and cats should be revaccinated every 3 years.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

No clinical signs other than those in section 3.6.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI07AA02

Inactivated viral vaccine for dogs and cats to stimulate active immunity against rabies.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product except other components recommended for use with the veterinary medicinal product mentioned in section 3.8 above.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 4 years.
Shelf life after first opening the immediate packaging: use immediately.

5.3 Special precautions for storage

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

Do not freeze.

5.4 Nature and composition of immediate packaging

Clear, hydrolytic glass Type I (Ph. Eur.) single dose vials with halogenobutyl rubber stopper, closed with a colour coded aluminium cap.

Cardboard box with 1 x 1 ml vial.
Cardboard or plastic box with 10 x 1 ml or 50 x 1 ml vials.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet Ireland Limited

7. MARKETING AUTHORISATION NUMBER(S)

VPA10996/170/001

8. DATE OF FIRST AUTHORISATION

10/08/2004

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

31/05/2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).