

## **SUMMARY OF PRODUCT CHARACTERISTICS**

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

Nobivac Rabies suspension for injection

### **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each 1 ml dose contains:

#### **Active substance:**

Rabies virus strain Pasteur RIV, inactivated:  $\geq 0.95$  AIU\* equivalent to  $\geq 2$  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: 0.60 - 0.88 mg Al<sup>3+</sup>

#### **Excipients:**

<b>Qualitative composition of excipients and other constituents</b>	<b>Quantitative composition if that information is essential for proper administration of the veterinary medicinal product</b>
Disodium hydrogen phosphate dihydrate	
Sodium dihydrogen phosphate dihydrate	
Thiomersal (preservative)	0.1 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 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.

### 3.3 Contraindications

None.

### 3.4 Special warnings

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.

### 3.5 Special precautions for use

#### Special precautions for safe use in the target species:

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

This veterinary medicinal product 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.

#### Special precautions for the protection of the environment:

Not applicable.

### 3.6 Adverse events

Very rare ( $< 1$ animal / 10 000 animals treated, including isolated reports):	Injection site swelling <sup>1</sup> Hypersensitivity reaction (e.g. facial oedema, vomiting, pruritus, diarrhoea) <sup>2</sup> Immune-mediated haemolytic anaemia, immune-mediated thrombocytopenia, immune-mediated polyarthritis. Lethargy <sup>3</sup> Anorexia <sup>3</sup> Hyperthermia <sup>3</sup>
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<sup>1</sup> Non-painful diffuse to firm swellings of approximately 1 cm in diameter may be observed for up to 3 weeks after subcutaneous vaccination.

<sup>2</sup> Such reaction 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 reaction occurs, appropriate treatment is recommended.

<sup>3</sup> Mild.

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 its local representative 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 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.

### **3.8 Interaction with other medicinal products and other forms of interaction**

Safety and efficacy data are available which demonstrate that the veterinary medicinal product 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 this vaccine can be administered at the same time but at different administration sites with vaccines in the Nobivac range that contain one or more of the following antigens: *Leptospira interrogans* serogroup Canicola serovar Portland-vere, *L. interrogans* serogroup Icterohaemorrhagiae serovar Copenhageni, *L. interrogans* serogroup Australis serovar Bratislava, and *L. kirschneri* serogroup Grippotyphosa serovar Dadas, although this may, in some instances, lead to vomiting.

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.

### **3.9 Administration routes and dosage**

Intramuscular or subcutaneous route.

Administer 1 dose (1 ml).

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 administration.

#### *Primary vaccination and revaccination in dogs and cats:*

Primary vaccination age: 12 weeks\* or older.

Revaccination: 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 for ferrets are available 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.

### **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**

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

## **5. PHARMACEUTICAL PARTICULARS**

### **5.1 Major incompatibilities**

Do not mix with any other veterinary medicinal products except components recommended for use 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 immediate packaging: once broached use immediately.

### **5.3 Special precautions for storage**

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

Do not freeze.

Protect from light.

#### **5.4 Nature and composition of immediate packaging**

Type I (Ph.Eur.) clear glass vial with halogenobutyl rubber stopper, closed with a colour coded aluminium cap.

*Package sizes:*

- Cardboard box with 1 x 1 ml vials.
- Cardboard or plastic (PET) 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 product 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 International B.V.

### **7. MARKETING AUTHORISATION NUMBER**

Vm 06376/4106

### **8. DATE OF FIRST AUTHORISATION**

25 October 2005

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

February 2026

## **10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT**

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on [www.gov.uk](http://www.gov.uk).

*Gavin Hall*

Approved: 25 February 2026