**IRISH MEDICINES BOARD ACT 1995**

**EUROPEAN COMMUNITIES (ANIMAL REMEDIES) (No. 2) REGULATIONS 2007**

**(S.I. No. 786 of 2007)**

VPA: **10996/170/001**
Case No: 7006799

The Irish Medicines Board in exercise of the powers conferred on it by Animal Remedies (No. 2) Regulations (S.I. No. 786 of 2007) hereby grants to:

**Intervet Ireland Limited**

**Magna Drive**, **Magna Business Park**, **Dublin 24**, **Ireland**

an authorisation, subject to the provisions of the said Regulations and the general conditions of the attached authorisation, in respect of the Veterinary Medicinal Product:

**Nobivac Rabies**

The particulars of which are set out in Part 1 and Part 2 of the said Schedule. The authorisation is also subject to any special conditions as may be specified in the said Schedule.

The authorisation,unless revoked, shall continue in force from **21/12/2009**.

Signed on behalf of the Irish Medicines Board

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A person authorised in that behalf by the said Board.

(NOTE: This authorisation replaces any previous authorisation in respect of this product which is now null and void.)

# Part II

# Summary of Product Characteristics

## 1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac Rabies

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml single dose contains:

**Active substance:**
Inactivated Rabies virus strain Pasteur RIV inducing at least 2 IU as measured in the potency test.

**Adjuvant:**
Aluminium phosphate 0.15 ml

**Excipients:**
Thiomersal 0.10 mg

For a full list of excipients see section 6.1.

## 3 PHARMACEUTICAL FORM

Suspension for injection

## 4 CLINICAL PARTICULARS

### 4.1 Target Species

Dogs and cats.

### 4.2 Indications for use, specifying the target species

For the active immunisation of dogs and cats to reduce mortality and clinical signs of rabies.
Onset of immunity: Protective levels of circulating antibody are seen in all species within 30 days of vaccination.
Duration of immunity: Studies indicate a minimum duration of protection in dogs and cats of 3 years.

### 4.3 Contraindications

None

### 4.4 Special warnings for each 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.

## 4.5 Special precautions for use

**Special precautions for use**

Only healthy animals should be vaccinated. 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 product to animals**

In the case of accidental self-injection, wash the area immediately with water. If symptoms develop, seek medical attention showing a copy of the product literature.

## 4.6 Adverse reactions (frequency and seriousness)

Transient local reactions such as diffuse to firm swellings 1 to 4 cm in diameter may be observed for up to 3 weeks after subcutaneous vaccination. The swellings may be painful for up to 3 days post dosing.
Hypersensitivity reactions may occur following vaccination. In the event of such reactions, administer an antihistamine, corticosteroid or adrenaline, without delay and by the most immediate route.

## 4.7 Use during pregnancy, lactation or lay

Can be used during pregnancy.

## 4.8 Interaction with other medicinal products and other forms of interaction

Safety and/or efficacy data are avaible which demonstrates that this vaccine can be mixed with Nobivac Tricat and 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).

## 4.9 Amounts to be administered and administration route

A single dose inoculation of 1 ml (one single dose vial) is sufficient irrespective of size, species or breed of animal. 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. Allow the vaccine to reach ambient temperature before use. Shake before and during use.

**Basic vaccination scheme**

**Dogs and Cats**

Animals less than 12 weeks of age:

*If born to un-vaccinated dams:* Primary vaccination may be administered by the intramuscular or subcutaneous route from 4 weeks of age.

*If born to vaccinated dams:* Since MDA could interfere with the response to vaccination, puppies and kittens born from rabies vaccinated dams should be vaccinated from 12 weeks of age or if vaccinated before this age should be given a second dose at 12 weeks of age.

Older animals:

Primary vaccination may be administered by the intramuscular or subcutaneous route from 12 weeks of age.

***Revaccination scheme***

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

## 4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

No effects other than those in section 4.6.

## 4.11 Withdrawal Period(s)

Not applicable.

## 5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

QI07A A02
The vaccine contains inactivated antigen to stimulate active immunity against rabies.

## 6 PHARMACEUTICAL PARTICULARS

## 6.1 List of excipients

Thiomersal
Disodium phosphate dihydrate
Sodium dihydrogen phosphate dihydrate
Water for injections

## 6.2 Incompatibilities

Do not mix with any other medicinal product except thosed listed in section 4.8.

## 6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 4 years

## 6.4 Special precautions for storage

Store in a refrigerator (2°C - 8°C). Do not freeze.

## 6.5 Nature and composition of immediate packaging

Clear, Glass Type II (Ph.Eur.) single dose vials with halogenobutyl rubber stopper, closed with a colour coded aluminium cap.
Cartons contain 1, 10 or 50 vials.
Not all pack sizes may be marketed.

## 6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Any unused product or waste material should be disposed of in accordance with national requirements.

## 7 MARKETING AUTHORISATION HOLDER

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

## 8 MARKETING AUTHORISATION NUMBER(S)

VPA 10996/170/001

## 9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

22nd May 2009

## 10 DATE OF REVISION OF THE TEXT

21st December 2009