Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac Rabies

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Per 1 mldose:

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 (preservative) 0.10 mg

For the 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 in animals

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 veterinary medicinal product to animals

In the case of accidental self-injection, wash the area immediately with water. If symptoms develop, seek medical attention and show the package leaflet or the label to the physician.

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 interactions

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.

4.9 Amounts to be administered and administration route

Dose: 1 ml irrespective of size, species or breed of animal.
Route: Intramuscular or subcutaneous injection.

Allow the vaccine to reach ambient 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 regime
Primary course
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 from 12 weeks of age.

Revaccination
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

Pharmacotherapeutic group: Inactivated viral vaccines, rabies virus.
ATCvet code: QI07AA02

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 Major incompatibilities

Do not mix with any other veterinary medicinal product except those 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, hydrolytic glass Type I (Ph. Eur.) single dose vials with halogenobutyl rubber stopper, closed with a colour coded aluminium cap.
Carton with 1 x 1 ml.
Carton or plastic box with 10 x 1ml or 50 x 1 ml.
Not all pack sizes may be marketed.

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

Any unused veterinary medicinalproduct or waste material derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Intervet Ireland Limited
Magna Drive
Magna Business Park, Citywest Road
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA10996/170/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 10 August 2004
Date of last renewal: 22 May 2009

10 DATE OF REVISION OF THE TEXT

February 2020