

IRISH MEDICINES BOARD ACT 1995

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

(S.I. No. 786 of 2007)

VPA: **10996/171/001**
Case No: 7005078

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 Tricat

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 previously revoked, shall continue in force from **23/02/2009**.

Signed on behalf of the Irish Medicines Board

A person authorised in that behalf by the said Board.

(NOTE: From this date of effect, 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 Tricat

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

<u>Active ingredients:</u>	per dose:
Feline viral rhinotracheitis virus	not less than $10^{4.5}$ TCID ₅₀ *
Feline calicivirus	not less than $10^{4.5}$ pfu**
Feline panleucopenia virus	not less than $10^{4.5}$ TCID ₅₀

*Tissue Culture Infective Dose 50%

** Plaque Forming Units

Excipients:

For a list of excipients, please see under section 6.1

3 PHARMACEUTICAL FORM

Lyophilisate for reconstitution for injection

4 CLINICAL PARTICULARS

4.1 Target Species

Cats

4.2 Indications for use, specifying the target species

For active immunity of cats to reduce clinical signs of feline viral rhinotracheitis and feline calicivirus infections and to reduce excretion of feline viral rhinotracheitis field virus.

Vaccination prevents feline panleucopenia infection.

To maintain protection a single annual booster dose is recommended.

Immunity develops by 7 days after the second vaccination of the primary course.

4.3 Contraindications

None

4.4 Special warnings for each target species

Contact with potential sources of respiratory infection should be avoided until 7 days after the second inoculation. Antiserum and immunosuppressive drugs may reduce the response to vaccination. 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. Immuno-competence 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

i) Special precautions for use in animals

Only healthy animals should be vaccinated.

Inadvertent nasal or oral dosing (eg by making an aerosol with the syringe, or the cat licking the injection site) may result in clinical signs of respiratory disease including lethargy and malaise. Care should be taken to ensure correct systemic administration of the vaccine. Swabbing the injection site with spirit after vaccination is a useful precaution.

ii) 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.

iii) other precautions

None

4.6 Adverse reactions (frequency and seriousness)

When reconstituted with Nobivac Solvent, a slight swelling (4mm) may be observed for one day at the site of injection in approximately 25% of the animals. This swelling may be painful at palpation.

When reconstituted with Nobivac Rabies, 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.

In the rare event of a hypersensitivity reaction following vaccination, administer an antihistamine, corticosteroid or adrenaline, without delay and by the most immediate route.

4.7 Use during pregnancy, lactation or lay

Do not use during pregnancy

4.8 Interaction with other medicinal products and other forms of interaction

Safety and/or efficacy data are available which demonstrate that this vaccine can be mixed with Nobivac Rabies.

4.9 Amounts to be administered and administration route

The contents of one vial of reconstituted vaccine should be injected subcutaneously or intramuscularly. Reconstitute immediately prior to use by the addition of the contents of one vial (1.0 ml) Nobivac Solvent or Nobivac Rabies. 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.

Basic vaccination scheme:

2 doses with an interval of 3 to 4 weeks between doses. The first dose may be administered to kittens from nine weeks of age.

Revaccination scheme:

To maintain protection a single annual booster dose is recommended.

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

A slight swelling (4mm) was observed for one day at the site of injection in approximately 50% of the animals which was painful at palpation.

A slight temperature elevation (40.1°C) was observed at first after inoculation, but disappeared within 24 hours.

4.11 Withdrawal Period(s)

Not applicable

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

ATC Code: QI06AD04

Vaccine contains attenuated antigens to stimulate active immunity against infectious respiratory disease caused by feline herpes virus (feline viral rhinotracheitis) and feline calicivirus and against feline panleucopenia (feline infectious enteritis).

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hydrolised gelatin,
sucrose,
di-Sodium hydrogen phosphate dihydrate,
water for injections.

6.2 Incompatibilities

Do not mix with any other product except Nobivac Rabies or with the solvent.

6.3 Shelf-life

Shelf life as packaged for sale: 24 months

Shelf-life after reconstitution: 30 minutes

6.4 Special precautions for storage

Store in a refrigerator (2°C to 8°C). Protect from light. Do not freeze.

Reconstituted vaccine:

Store in a refrigerator (2°C to 8°C) with care being taken to avoid prolonged or repetitive exposure to high ambient temperatures following withdrawal from the refrigerator prior to use.

6.5 Nature and composition of immediate packaging

Single dose glass vials type I (Ph.Eur) with halogenobutyl rubber stopper, closed with a colour coded aluminium cap.

Pack sizes:

Cartons of 5 vials vaccine and 5 vials of solvent (Nobivac Solvent)

Cartons of 25 vials vaccine and 25 vials of solvent (Nobivac Solvent)

Cartons of 10 vials vaccine

Cartons of 50 vials vaccine

Not all presentation may be marketed.

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

Dispose of waste material by boiling, incineration or immersion in an appropriate disinfectant approved for use by the competent authorities.

7 MARKETING AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10996/171/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

23rd February 2009

10 DATE OF REVISION OF THE TEXT