IRISH MEDICINES BOARD ACT 1995

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

(S.I. No. 786 of 2007)

VPA: **10996/176/001**
Case No: 7003404

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 Pi

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 **26/08/2008**.

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 Pi

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:
Live attenuated canine parainfluenza virus (CPi) strain Cornell: ≥5.5 $\log_{10}$ and ≤ 7.3 $\log_{10}$ $TCID_{50}$*

*TCID50 = median Tissue Culture Infective Dose

Excipients:

For a full list of excipients, see section 6.1.

Solvent:
Nobivac Solvent (Phosphate buffered diluent)

3 PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for injection.
Lyophilisate: pale yellow grey pellet
Solvent: clear colourless solution
Reconstituted product: pale yellow to pink suspension

4 CLINICAL PARTICULARS

4.1 Target Species

Dogs.

4.2 Indications for use, specifying the target species

For active immunisation of dogs from the age of 8 weeks onwards to reduce clinical signs of canine para-influenza infection and to reduce viral shedding.

Onset of immunity: 4 weeks after vaccination.

Duration of immunity: has not been demonstrated, but an anamnestic response is produced in dogs given a revaccination one year after basic vaccination.

4.3 Contraindications

None.

4.4 Special warnings for each target species

A protective antibody titre is not accomplished in all vaccinated dogs.

As maternally derived passive antibodies can interfere with the response to vaccination in very young animals, a final dose at 10 weeks of age or older is recommended.

4.5 Special precautions for use

Special precautions for use in animals
Vaccinate only healthy dogs.
Sterile equipment should be used for administration.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

In the case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician

4.6 Adverse reactions (frequency and seriousness)

Some dogs may show discomfort during injection.
A diffuse swelling, up to 5 mm in diameter, may be observed at the site of injection. Occasionally this swelling may be hard and painful and last for up to 3 days post injection.
After subcutaneous administration with the lepto and/or rabies vaccines of the Nobivac series (where these products and their combined use are authorised), a diffuse swelling may be observed at the injection site in most puppies. Occasionally this swelling may be hard, painful and more severe but this will diminish gradually and disappear after 2-3 weeks.
Hypersensitivity reactions may occur. In the event of an anaphylactic reaction appropriate treatment such as adrenaline should be administered without delay.

4.7 Use during pregnancy, lactation or lay

Nobivac Pi has been shown to be safe for use in pregnant bitches that have been vaccinated before pregnancy with the Pi vaccine of the Nobivac series.

4.8 Interaction with other medicinal products and other forms of interaction

No information is available on the compatibility of this vaccine with any other except the lepto and/or rabies vaccines of the Nobivac series. These liquid vaccines can be used to reconstitute the freeze-dried Nobivac Pi, where these products and their combined use are authorised. Therefore the safety and efficacy of this product when used with any other vaccine than these (either when used on the same day or at different times) has not been demonstrated.

4.9 Amounts to be administered and administration route

One ml solvent must be used to reconstitute the freeze-dried Nobivac Pi vaccine.
One ml of the reconstituted vaccine should be given by subcutaneous injection.

Vaccination schedule:
- Basic vaccination:
    - Before the age of 12 weeks:
      Two vaccinations, each with a single dose: the first vaccination from the age of 8 weeks onwards and the second vaccination 2-4 weeks later.
    - From the age of 12 weeks onwards:
      Single vaccination, with one dose per animal
- Revaccination:
  Every year with a single dose.

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

Not different from a single dose. In some dogs the swelling may be more painful or may be observed for a longer period.

4.11 Withdrawal Period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Live viral vaccine.
ATCvet code: QI07AD08

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Vaccine:
Sorbitol, gelatin, pancreatic digest of casein, disodium phosphate dihydrate, water for injection
Solvent:
Disodium phosphate dihydrate, potassium dihydrogen phosphate, water for injection

6.2 Incompatibilities

Do not mix with any other vaccine except the diluent supplied with the product or with the lepto and/or rabies vaccines of the Nobivac series (where these products and their combined use are authorised).

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale
2 years at 2-8°C (after storage by the manufacturer for 29 months at -20°C)

Shelf-life after dilution or reconstitution according to directions
Use within 30 minutes.

Shelf life of the solvent
4 years.

6.4 Special precautions for storage

Vaccine:
Store in original package at 2-8°C (in a refrigerator). Do not freeze. Keep protected from light. Care should be taken to avoid prolonged or repetitive exposure to high ambient temperatures following withdrawal from the refrigerator prior to use.
Solvent:
The solvent may be stored together with the vaccine in the refrigerator but can also be kept independently at 15-25°C.

6.5 Nature and composition of immediate packaging

Vaccine:
Vial of hydrolytical class type I (Ph. Eur.) glass, containing the freeze-dried pellet. The vial is closed with a halogenobu rubber bung and sealed with a coded aluminium cap.
Solvent:
Vial of hydrolytical class type I (Ph. Eur.) glass, containing the solvent. The vial is closed with a halogenobutyl rub bung and sealed with a coded aluminium cap.

Nobivac Pi and the solvent are presented in cartons containing 5, 10, 25 or 50 single doses. Not all presentations may 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 competent authorities.

7 MARKETING AUTHORISATION HOLDER

Intervet Ireland Limited
Magna Drive
Magna Business Park
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10996/176/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

26th August 2008

10 DATE OF REVISION OF THE TEXT

22nd September 2008