1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac Pi lyophilisate and solvent for suspension for injection for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (1 ml) of reconstituted vaccine contains:

Active substance:
Canine parainfluenza virus, strain Cornell, live attenuated: ≥ 5.5 $\log_{10}$ and ≤ 7.3 $\log_{10}$ $TCID_{50}$*

* $TCID_{50}$ = median Tissue Culture Infective Dose

Excipients:

Qualitative composition of excipients and other constituents
Lyophilisate:
Sorbitol
Gelatin
Pancreatic digest of casein
Disodium phosphate dehydrate
Water for injections
Solvent:
Disodium phosphate dihydrate
Potassium dihydrogen phosphate
Water for injections

Lyophilisate: off-white or cream-coloured pellet.
Solvent: clear colourless solution.

3. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each target species

For active immunisation of dogs from the age of 8 weeks onwards to reduce clinical signs of canine parainfluenza 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 1 year after basic vaccination.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

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.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Not applicable.

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

Dogs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Discomfort[1]. Injection site swelling[2]. Hypersensitivity reaction[3].

[1] During injection.
[2] Diffuse, up to 5 mm in diameter, which may occasionally be hard and painful and last up to 3 days post injection.
[3] In the event of an anaphylactic reaction, appropriate treatment such as adrenaline should be administered without delay.

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

3.8 Interaction with other medicinal products and other forms of interaction

Safety and efficacy data (viral excretion) are available which demonstrate that this vaccine can be mixed and administered with the inactivated vaccines in the Nobivac range against canine leptospirosis caused by all or some of the following serovars: *L. interrogans* serogroup Canicola serovar Canicola, *L. interrogans* serogroup Icterohaemorrhagiae serovar Copenhageni, *L. interrogans* serogroup Australis serovar Bratislava, and *L. kirschneri* serogroup Grippotyphosa serovar Bananal/Liangguang.

The product information of the relevant Nobivac vaccines should be consulted before administration of the mixed product. When mixed with Nobivac leptospirosis vaccines at annual revaccination, it has been established that there is no interference with the anamnestic response induced by the injectable canine parainfluenza virus component.

After administration with one of the leptospirosis vaccines, a mild and transient increase in body temperature (≤ 1 °C) may occur for a few days after vaccination, with some pups showing less activity and/or a reduced appetite. A small transient swelling (≤ 4 cm), which can occasionally be firm and painful on palpation, may be observed at the site of injection. Any such swelling will either have disappeared or be clearly diminished by 14 days post-vaccination.
After mixed administration of an overdose of this vaccine and an overdose of the leptospirosis vaccines in the Nobivac range, transient local reactions such as diffuse to firm swellings from 1 to 5 cm in diameter may be observed, usually these will persist no longer than 5 weeks, however some may take a little longer to completely disappear.

Safety and efficacy data are available which demonstrate that this vaccine can be mixed and administered with the inactivated vaccine in the Nobivac range against rabies or the inactivated vaccine against rabies and leptospirosis, where applicable. After administration with the rabies containing vaccines transient local reactions such as diffuse to firm swellings from 1 to 4 cm in diameter may be observed for up to 3 weeks after vaccination. The swellings may be painful for up to 3 days post dosing.

Safety data are available which demonstrate that this vaccine can be administered at the same time but not mixed with the inactivated vaccine in the Nobivac range against *Bordetella bronchiseptica*.

When this vaccine is administered in association with the inactivated vaccine in the Nobivac range against *Bordetella bronchiseptica*, the demonstrated antibody response data of this vaccine are the same as when this vaccine is administered alone.

When this vaccine is used with any of the other Nobivac vaccines referred to above, the minimum vaccination age for each vaccine must be taken into account such that at the time of vaccination, the dogs are at or older than the oldest minimum vaccination age for the individual vaccines.

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

One ml solvent or 1 ml (1 dose) of inactivated vaccine (as specified in section 3.8) must be used to reconstitute this freeze-dried vaccine.
One dose (1 ml) of reconstituted vaccine should be given by subcutaneous injection. Sterile equipment should be used for administration.

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.

Reconstituted product: off-pink or pink suspension.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

No adverse events other than those mentioned in section 3.6, except that the swelling may be more painful or may be observed for a longer period, were observed after administration of a 10-fold overdose of the vaccine.

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: QI07AD08.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product, except the solvent supplied with the product or other Nobivac dog vaccines mentioned in section 3.8 above (where these products are authorised).

5.2 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 reconstitution according to directions: use within 30 minutes.

Shelf life of the solvent: 4 years.

5.3 Special precautions for storage

Lyophilisate:
Store in a refrigerator (2 °C – 8 °C).
Do not freeze.
Protect 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:
Store below 25 °C if stored independently from the lyophilisate.

5.4 Nature and composition of immediate packaging

Lyophilisate:
Vial of hydrolytical class type I (Ph. Eur.) glass closed with a halogenobutyl rubber stopper and a colour coded aluminium cap.

Solvent:

Vial of hydrolytical class type I (Ph. Eur.) glass closed with a halogenobutyl rubber stopper and a colour coded aluminium cap.

Pack sizes:
Cardboard or plastic box with 5, 10, 25 or 50 single dose vials.
Solvent may be packed together with the vaccine or separately.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products 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 Ireland Limited

7. MARKETING AUTHORISATION NUMBER(S)

VPA10996/289/001

8. DATE OF FIRST AUTHORISATION

14 April 2022

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

09 December 2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).