1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac Pi lyophilisate and solvent for suspension for injection for dogs.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 dose of 1 ml contains:

Active substance:
Live attenuated canine parainfluenza virus (CPi) strain Cornell: ≥5.5 $\log_{10}$ and ≤7.3 $\log_{10}$ $TCID_{50}$*.
* $TCID_{50}$ = median Tissue Culture Infective Dose

Solvent:
Nobivac Solvent (Phosphate buffered diluent).

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for injection.

Lyophilisate: off-white or cream-coloured pellet.
Solvent: clear colourless solution.
Reconstituted product: off-pink or 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)

In very rare cases, some dogs may show discomfort during injection.
In very rare cases, 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.
In very rare cases, hypersensitivity reactions may occur. In the event of an anaphylactic reaction appropriate treatment such as adrenaline should be administered without delay.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

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

Safety and efficacy data (viral excretion) are available which demonstrate that this vaccine can be mixed and administered with the inactivated vaccines of the Nobivac series 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 Nobivac Pi and an overdose of the leptospirosis vaccines of the Nobivac series, 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 of the Nobivac series 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 of the Nobivac series against *Bordetella bronchiseptica*.

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

When Nobivac Pi 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 compatibility 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.

4.9 Amounts to be administered and administration route

One ml solvent or 1 ml (1 dose) of inactivated vaccine (as specified in section 4.8) must be used to reconstitute the freeze-dried Nobivac Pi vaccine.
One dose (1 ml) of 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. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Live viral vaccine for dogs.
ATCvet code: QI07AD08.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Vaccine:
Sorbitol
Gelatin
Pancreatic digest of casein
Disodium phosphate dehydrate
Water for injections

Solvent:
Disodium phosphate dihydrate
Potassium dihydrogen phosphate
Water for injections

6.2 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 4.8 (where these products 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 reconstitution according to directions: Use within 30 minutes.

Shelf-life of the solvent: 4 years.

6.4. Special precautions for storage

Vaccine:
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 vaccine.

6.5 Nature and composition of immediate packaging

Vaccine:
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: Carton 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.

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

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 International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

represented by the national companies

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: {DD/MM/YYYY}
Date of last renewal: {DD/MM/YYYY}

10 DATE OF REVISION OF THE TEXT

{MM/YYYY}

PROHIBITION OF SALE, SUPPLY AND/OR USE

Veterinary medicinal product subject to prescription.