# SUMMARY OF PRODUCT CHARACTERISTICS

## 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<br>(<1 animal / 10,000 animals treated, including isolated reports): | Discomfort[1].<br>Injection site swelling[2].<br>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.
{< > to be adjusted nationally}

### 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.
{to be completed nationally}

### 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>.
{< > to be adjusted nationally}

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

{Name}
{to be completed nationally}

## 7. MARKETING AUTHORISATION NUMBER(S)

{to be completed nationally}

## 8. DATE OF FIRST AUTHORISATION

Date of first authorisation: {DD/MM/YYYY}.
{to be completed nationally}

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

{MM/YYYY}
{to be completed nationally}

## 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).

**LABELLING AND PACKAGE LEAFLET**

# A. LABELLING

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**Cardboard or plastic box**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac Pi lyophilisate and solvent for suspension for injection

## 2. STATEMENT OF ACTIVE SUBSTANCES

Each dose (1 ml) contains:

Canine parainfluenza virus, strain Cornell, live attenuated: 5.5 - 7.3 $\log_{10}$ $TCID_{50}$

## 3. PACKAGE SIZE

5x 1 dose
10x 1 dose
25x 1 dose
50x 1 dose

## 4. TARGET SPECIES

Dogs.

## 5. INDICATIONS

## 6. ROUTES OF ADMINISTRATION

Subcutaneous use.

## 7. WITHDRAWAL PERIODS

## 8. EXPIRY DATE

Exp. {mm/yyyy}
Once reconstituted use within 30 minutes.

## 9. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator.
Do not freeze.
Protect from light.

## 10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

## 11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

## 12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

## 13. NAME OF THE MARKETING AUTHORISATION HOLDER

{Name or company name or logo name of the marketing authorisation holder}
{to be completed nationally}

## 14. MARKETING AUTHORISATION NUMBERS

{national number}
{to be completed nationally}

## 15. BATCH NUMBER

Lot {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

**Glass vial label - Lyophilisate (vial with 1 dose)**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac Pi 

## 2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Per dose:
Live CPi: 5.5 - 7.3 $\log_{10}$ $TCID_{50}$.

1 dose

## 3. BATCH NUMBER

Lot {number}

## 4. EXPIRY DATE

Exp. {mm/yyy}
Once reconstituted use within 30 minutes.

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

**Glass vial label - Solvent (vial with 1 dose)**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac Solvent
– sterile buffered solution

## 2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

1 dose
(1ml)

## 3. BATCH NUMBER

Lot {number}

## 4. EXPIRY DATE

Exp. {mm/yyy}

# B. PACKAGE LEAFLET

# PACKAGE LEAFLET

## 1. Name of the veterinary medicinal product

Nobivac Pi lyophilisate and solvent for suspension for injection for dogs

## 2. 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

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

## 3. Target species

Dogs.

## 4. Indications for use

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.

## 5. Contraindications

None.

## 6. Special warnings

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.

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.

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

Interaction with other medicinal products and other forms of interaction:
For the veterinarian only:

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 in the other Nobivac range 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.

Overdose:
No adverse events other than those mentioned in section adverse events, 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.

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

## 7. Adverse events

Dogs:

| | |
|---|---|
| Very rare<br>(<1 animal / 10,000 animals treated, including isolated reports): | Discomfort[1].<br>Injection site swelling[2].<br>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 product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder <or the local representative of the marketing authorisation holder> using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

{< > to be adjusted nationally}

## 8. Dosage for each species, routes and method of administration

One ml solvent or 1 ml (1 dose) of inactivated vaccine (as specified in the above section) 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 coloured suspension.

## 9. Advice on correct administration

Allow the solvent to reach ambient temperature before use.

## 10. Withdrawal periods

Not applicable.

## 11. Special storage precautions

Keep out of the sight and reach of children.

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.

Do not use this veterinary medicinal product after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

Shelf life after reconstitution according to directions: 30 minutes.

## 12. Special precautions for disposal

Medicines should not be disposed of via wastewater <or household waste>.
{< > to be adjusted nationally}

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 applicable national collection systems. These measures should help to protect the environment.

## 13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

## 14. Marketing authorisation numbers and pack sizes

{to be completed nationally}
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.

## 15. Date on which the package leaflet was last revised

{MM/YYYY}
{to be completed nationally}

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

## 16. Contact details

Marketing authorisation holder <and manufacturer responsible for batch release> <and contact details to report suspected adverse reactions>:
{< > to be adjusted nationally}

<Manufacturer responsible for batch release:> {to be adjusted nationally if included in the above}
Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

<Local representative< and contact details to report suspected adverse reactions>:
{< > to be adjusted nationally}

<For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.>
{< > to be adjusted nationally}

## 17. Other information

{to be completed nationally}