PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton or plastic box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac Pi.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Per dose of 1 ml:
Live CPi virus, strain Cornell: 5.5 - 7.3 $\log_{10}$ $TCID_{50}$.

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for injection.

4. PACKAGE SIZE

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

5. TARGET SPECIES

Dogs.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous use.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once reconstituted use within 30 minutes.

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Read the package leaflet before use.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Limited
Walton Manor
Walton
Milton Keynes
MK7 7AJ

16. MARKETING AUTHORISATION NUMBER

Vm 01708/4632

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac Pi.

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

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

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

1 dose.

4. ROUTE(S) OF ADMINISTRATION

SC

5. WITHDRAWAL PERIOD

Not applicable.

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}
Once reconstituted use within 30 minutes.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PACKAGE LEAFLET

Nobivac Pi Lyophilisate and Solvent for Suspension for Injection for Dogs.

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
MSD Animal Health UK Limited
Walton Manor
Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

Manufacturer responsible for batch release:
Intervet International B.V.
Wim de Körverstraat 35
NL - 5831 AN BOXMEER

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

1 dose of 1 ml contains:

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

Solvent:
Nobivac Solvent (Phosphate buffered diluent).

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

4. INDICATION(S)

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.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

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.
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

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).

7. TARGET SPECIES

Dogs.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

One ml solvent or 1 ml (1 dose) of inactivated vaccine (as specified in section 12) must be used to reconstitute the freeze-dried Nobivac Pi vaccine.
One ml (1 ml) of reconstituted vaccine should be given by subcutaneous injection.

<u>Vaccination schedule:</u>
- 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.

9. ADVICE ON CORRECT ADMINISTRATION

Allow the solvent to reach ambient temperature before use.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Vaccine: Store in a refrigerator (2 – 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.

Do not use this veterinary medicinal product after the expiry date which is stated on the label.

Shelf life after reconstitution according to directions: 30 minutes.

12. SPECIAL WARNING(S)

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.

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

Pregnancy:
Nobivac Pi 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 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.

Overdose (symptoms, emergency procedures, antidotes):
Not different from a single dose. In some dogs the swelling may be more painful or may be observed for a longer period.

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).

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIAL, IF ANY

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

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.

Veterinary medicinal product subject to prescription.

POM-V
To be supplied only on veterinary prescription.

MA number Vm 01708/4632

Distributor in Northern Ireland:
Intervet Ireland Ltd.
Magna Drive
Magna Business Park
Citywest Road
Dublin 24
Ireland

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