1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac DHPPi lyophilisate for suspension for injection for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (1 ml) of reconstituted vaccine contains:

Active substances:
Canine distemper virus ≥ $10^{4.0}$ $TCID_{50}$*
Canine adenovirus 2 ≥ $10^{4.0}TCID_{50}$*
Canine parvovirus ≥ $10^{7.0}$ $TCID_{50}$*
Canine parainfluenzavirus ≥ $10^{5.5}$ TCID50*

*$TCID_{50}$: Tissue culture infective dose 50%

Excipients:

Qualitative composition of excipients and other constituents
Sorbitol
Gelatin
Pancreatic digest of casein
Disodium phosphate dihydrate.

Lyophilisate: off-white or cream-coloured pellet.

3. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each target species

For the active immunisation of dogs to reduce clinical signs of disease caused by canine distemper virus infection, to prevent clinical signs and reduce viral excretion caused by canine parvovirus infection, to reduce clinical signs and/or virus excretion caused by canine parainfluenza virus infection; to reduce clinical signs of canine contagious hepatitis and viral excretion due to canine adenovirus 1 infection and to reduce clinical signs of respiratory infection and viral excretion caused by adenovirus type 2 infection.

Onset of immunity: CDV and CPV one week, CAV2 two weeks, and CPi four weeks after vaccination.

Duration of immunity: CDV, CAV2 and CPV: at least three years.
CPi: has not been established, but an anamnestic response is produced in dogs given a revaccination one year after basic vaccination.

3.3 Contraindications

None.

3.4 Special warnings

A good immune response is reliant on the reaction of an immunogenic agent and a fully competent immune system. Immunogenicity of the vaccine antigen will be reduced by poor storage or inappropriate administration.
Immuno-competence of the animal may be compromised by a variety of factors including poor health, nutritional status, genetic factors, concurrent drug therapy and stress.
Vaccinate healthy animals only.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Vaccinated dogs may excrete the CPV vaccine strain at very low levels for up to 8 days following vaccination. However, there is no evidence of any reversion to virulence of the vaccine strain and therefore no need to separate unvaccinated dogs from contact with recently vaccinated individuals.
Keep vaccinated dogs from exposure to canine parainfluenzavirus for four weeks, canine adenovirus infection for two weeks and canine parvovirus and canine distemper virus infection for one week after vaccination. The vaccine may not be effective in dogs incubating the disease at the time of vaccination.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In the case of accidental self-injection, wash the area immediately with water. If symptoms develop, seek medical attention 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:

Common (1 to 10 animals / 100 animals treated):	Injection site swelling[1,2].
Rare (1 to 10 animals / 10,000 animals treated):	Hypersensitivity reaction[3].

[1]After subcutaneous administration with Nobivac Solvent or Nobivac Lepto 2: Up to 5 mm in diameter, occasionally may be hard and painful and last for up to 3 days.
[2]After subcutaneous administration with Nobivac Rabies: 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.
[3]Administer an antihistamine, corticosteroid or adrenaline, without delay and by the most immediate route.

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 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:
Can be used during pregnancy.

3.8 Interaction with other medicinal products and other forms of interaction

Safety and efficacy data are available which demonstrate that this vaccine can be mixed with Nobivac Rabies, Nobivac Lepto 2 or Nobivac Lepto 4.
The product information of the relevant Nobivac vaccines should be consulted before administration of the mixed product.

Concurrent use with Nobivac leptospirosis vaccines:
Safety and efficacy data 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.
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.

Safety data and efficacy data for the canine distemper virus, canine adenovirus and canine parvovirus components of this vaccine 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 for the live canine parainfluenza component of this vaccine are the same as when this vaccine is administered alone.

When Nobivac DHPPi 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 decided on a case by case basis.

Antiserum and immunosuppressive drugs may reduce the response to vaccination.

3.9 Administration routes and dosage

Subcutaneous use.
Administer 1 dose (1 ml).

Reconstitute immediately prior to use by the addition of the contents of one vial (1.0 ml) of Nobivac Solvent or one of the compatible vaccines (Nobivac Lepto 2, Nobivac Lepto 4 or Nobivac Rabies).
Sterile equipment should be used for administration.
Avoid contamination of vaccine with traces of chemical sterilising agents.
Do not use chemicals such as disinfectant or spirit to disinfect the skin prior to inoculation.

Primary vaccination
Puppies from 6 weeks of age can be vaccinated with Nobivac DHPPi.
Where early protection is required against canine distemper, adenovirus and parvovirus, the first dose of these components is recommended from 6 weeks of age but, because maternally derived antibody can interfere with the response to vaccination, a final dose should be administered at 10 weeks of age or older.

A single dose of the canine distemper, adenovirus and parvovirus components of Nobivac DHPPi is sufficient to establish immunity in dogs of 10 weeks of age or older.
Use of Nobivac DHP should be considered in these animals.
For the parainfluenza component of Nobivac DHPPi, a single dose from the age of 12 weeks is sufficient to establish immunity. In animals younger than 12 weeks, 2 doses of this component are recommended so that the first dose is administered from the age of 8 weeks onwards, and the second dose, 2 – 4 weeks later.

In summary:
-Animals 6 – 10 weeks of age: 2 doses of Nobivac DHPPi, 2 – 4 weeks apart such that the second dose is given from 10 weeks of age.
For protection against parainfluenza, the first dose should be administered ≥ 8 weeks.
-Animals 10 – 12 weeks of age: 2 doses of Nobivac DHPPi, 2 – 4 weeks apart.
-Animals ≥ 12 weeks of age: 1 dose of Nobivac DHPPi.

Revaccination
It is recommended that a single booster dose is given as follows: Canine distemper, adenovirus and parvovirus: every 3 years.
Canine parainfluenza: every year.

Reconstituted product: off-pink or pink coloured suspension.

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

After mixed administration of an overdose of Nobivac DHPPi 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.

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:

QI07AD04

The vaccine contains attenuated antigens to stimulate active immunity in dogs against canine distemper virus, canine parvovirus, canine parainfluenza virus and canine contagious hepatitis caused by canine adenovirus 1 and respiratory disease caused by canine adenovirus type 2. Under laboratory conditions, antibody response, reduction of clinical signs and/or reduction of virus excretion have been observed after challenge with CPi virus 4 weeks after vaccination. It was not possible to produce clinical signs by CPi challenge in adult dogs and duration of immunity could therefore not be demonstrated, but an anamnestic response was seen in dogs given a revaccination one year after basic vaccination.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product except Nobivac Lepto 2, Nobivac Lepto 4, Nobivac Rabies or Nobivac Solvent.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after reconstitution according to directions: 30 minutes.

5.3 Special precautions for storage

Store in a refrigerator (2 °C – 8 ° C).
Do not freeze.
Protect from light.

Reconstituted vaccine: Store in a refrigerator (2°C - 8°C) with care being taken to avoid prolonged or repetitive exposure to high ambient temperatures following withdrawal from the refrigerator prior to use.

5.4 Nature and composition of immediate packaging

Clear, glass (Type I Ph.Eur) vials with halogenobutyl rubber stopper, closed with a colour coded aluminium cap.

Pack sizes:
Cartons or plastic box with 10 or 50 single dose vials of vaccine lyophilisate.

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)

VPA10996/166/001

8. DATE OF FIRST AUTHORISATION

03 June 2005

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

16 April 2025

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).