Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac DHPPi

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Per 1 ml dose of reconstituted vaccine:
Active substance:

Canine distemper virus	not less than $10^{4.0}$ $TCID_{50*}$
Canine adenovirus 2	not less than $10^{4.0}$ $TCID_{50*}$
Canine parvovirus	not less than $10^{7.0}$ $TCID_{50*}$
Canine parainfluenzavirus	not less than $10^{5.5}$ $TCID_{50*}$

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

Excipients:
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Lyophilisate for reconstitution for injection.

4 CLINICAL PARTICULARS

4.1 Target Species

Dogs.

4.2 Indications for use, specifying the 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 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

The CPV vaccine strain may be shed at very low levels for up to 8 days after inoculation. 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.
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.

4.5 Special precautions for use

Special precautions for use in animals
Only healthy dogs should be vaccinated. 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 dosing. 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.

4.6 Adverse reactions (frequency and seriousness)

After subcutaneous administration with Nobivac Solvent or Nobivac Lepto 2, a diffuse swelling, up to 5 mm in diameter, may be observed at the site of injection in approximately 10% of the animals. Occasionally this swelling may be hard and painful and last for up to 3 days post injection.
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 post dosing.
In the rare event of a hypersensitivity reaction following vaccination, administer an antihistamine, corticosteroid or adrenaline, without delay and by the most immediate route.

4.7 Use during pregnancy, lactation or lay

Can be used during pregnancy.

4.8 Interaction with other medicinal products and other forms of interaction

Safety and/or 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.
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.

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.
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.

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.

4.9 Amounts to be administered and administration route

The contents of one vial of reconstituted vaccine should be injected subcutaneously.

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.

Vaccination regime
Primary course
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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

None other than those mentioned in section 4.6.

4.11 Withdrawal Period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group:
Immunologicals for canidae, dog, live viral vaccines, canine distemper virus + canine adenovirus + canine parvovirus + canine parainfluenza virus.

ATC vet code: QI07AD04

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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sorbitol
Gelatin
Pancreatic digest of casein
Disodium phosphate dihydrate.

6.2 Incompatibilities

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

6.3 Shelf-life

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

6.4 Special precautions for storage

Store in a refridgerator (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.

6.5 Nature and composition of immediate packaging

Clear, glass (Type I Ph.Eur) vials with halogenobutyl rubber stopper, closed with a colour coded aluminium cap.
Cartons or plastic box with 10 or 50 single dose vials of vaccine lyophilisate.

Not all presentations may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Intervet Ireland Ltd.
Magna Drive
Magna Business Park
Citywest Road
Dublin 24

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10996/166/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 3rd June 2005

Date of last renewal: 14th May 2010

10 DATE OF REVISION OF THE TEXT

September 2016