# Summary of Product Characteristics

## 1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac DHP

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

*Active substances:*
Per dose of 1ml reconstituted vaccine:

| | |
|---|---|
| Canine distemper virus, strain Onderstepoort | not less than $10^{4.0}$ $TCID_{50*}$ |
| Canine adenovirus 2, strain Manhattan LPV3 | not less than $10^{4.0}$ $TCID_{50*}$ |
| Canine parvovirus, strain 154 | not less than $10^{7.0}$ $TCID_{50*}$ |

*Tissue culture infective dose 50%

*Solvent (1ml per vial):*
Phosphate buffered saline
*Excipients:*
For a full list of excipients see Section 6.1

## 3 PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension 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 viral excretion caused by canine parvovirus 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.

Specific claims:
Onset of immunity: one week.
Duration of immunity: three years.

### 4.3 Contraindications

None.

### 4.4 Special warnings for each target species

The efficacy of the CDV, CAV2 and CPV components of the vaccine may be reduced due to maternal antibody interference. However, the vaccine has been proven to be of benefit against virulent challenge in the presence of maternal antibody levels to CDV, CAV2 and CPV that are likely to be encountered under field conditions.

### 4.5 Special precautions for use

*Special precautions for use in animals*
Only healthy dogs should be vaccinated. Dogs should not be exposed to unnecessary risk of infection within the first week after completion of the vaccination regimen.

While the canine parvovirus vaccine strain may be shed at very low levels for up to 8 days after inoculation, there is no evidence that this results in clinical symptoms if non-vaccinated animals are infected.

*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 to the physician.

**4.6 Adverse reactions (frequency and seriousness)**

A common reaction after subcutaneous administration with the diluent provided is a diffuse swelling up to 5 mm in diameter at the site of injection. Occasionally this swelling may be hard and painful and last for up to 3 days post injection.
In rare cases a transient rise in body temperature and/or a transient acute hypersensitivity reaction (anaphylaxis)- with signs that may include lethargy, facial oedema, pruritus, dyspnoea, vomiting, diarrhoea or collapse - may occur shortly after vaccination.

**4.7 Use during pregnancy, lactation or lay**

Can be used in pregnant bitches which have previously been vaccinated with the CDV (strain Onderstepoort), CAV2 (strain Manhattan LPV3) and CPV (strain 154) antigens included in the Nobivac vaccine series.

**4.8 Interaction with other medicinal products and other forms of interactions**

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.

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 DHP 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. After administration with the rabies vaccine, where this product is authorised, 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 and efficacy data are available which demonstrate that this vaccine can be administered on the same day, but not mixed, with the live vaccine for intranasal administration of the Nobivac series against infectious tracheobronchitis caused by *Bordetella bronchiseptica* and/or canine parainfluenza virus.

When Nobivac DHP 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.

Consult product leaflets before administering products simultaneously.

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.

**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 the diluent provided or the vaccines of the Nobivac series against rabies or leptospirosis as mentioned in Section 4.8 (where these products are authorised). 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 vaccination:**

A single injection should establish active immunity in dogs of 10 weeks of age or older. Where earlier protection is required a first dose may be given to puppies from 6 weeks of age, but because maternally derived passive antibody can interfere with the response to vaccination a final dose should be given 2–4 weeks later i.e. at 10 weeks of age or older.

**Booster vaccination:**

To maintain protection a single booster dose is recommended every three years.

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

No effects other than those given in section 4.6.

**4.11 Withdrawal period(s)**

Not applicable.

**5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES**

Pharmacotherapeutic group: live viral vaccines
ATCvet code: QI07AD02The vaccine contains attenuated antigens to stimulate active immunity in dogs against canine distemper virus, canine parvovirus, canine contagious hepatitis caused by canine adenovirus 1 and respiratory disease caused by canine adenovirus type 2.

**6 PHARMACEUTICAL PARTICULARS**

**6.1 List of excipients**

Gelatin
Sorbitol
Pancreatic digest of casein
Disodium phosphate dihydrate
Potassium dihydrogen phosphate
Water for injections

**6.2 Major incompatibilities**

Do not mix with any other veterinary medicinal product except with the diluent provided or the vaccine of the Nobivac series 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: 24 months
Shelf life after reconstitution: 30 minutes

**6.4 Special precautions for storage**

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

**6.5 Nature and composition of immediate packaging**

Clear, Glass Type I (Ph. Eur.) single vials with halogenobutyl rubber stopper, closed with a colour coded aluminium cap. Cardboard or plastic box containing 10 or 50 single dose vials. The diluent may be packed together with the vaccine or separately. Not all presentations may be marketed.

**6.6 Special precautions for the disposal of unused veterinary medicinal products 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 Ireland Limited
Magna Drive
Magna Business Park, Citywest Road
Dublin 24
Ireland

**8 MARKETING AUTHORISATION NUMBER(S)**

VPA10996/174/001

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 12 November 2004
Date of last renewal: 12November 2009

**10 DATE OF REVISION OF THE TEXT**

January 2015