SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac DHP lyophilisate and solvent for suspension for injection for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (1 ml) of reconstituted vaccine contains:

Active substances:

Canine distemper virus, strain Onderstepoort	≥ $10^{4.0}$ $TCID_{50*}$
Canine adenovirus 2, strain Manhattan LPV3	≥ $10^{4.0}$ $TCID_{50*}$
Canine parvovirus, strain 154	≥ $10^{7.0}$ $TCID_{50*}$

*Tissue culture infective dose 50%

Excipients:

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

Onset of immunity: 1 week.
Duration of immunity: 3 years.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

The efficacy of the CDV, CAV_2 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, CAV_2 and CPV that are likely to be encountered under field conditions.

3.5 Special precautions for use

Special precautions for safe use in the target species:
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 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.

Other precautions:
Not applicable.

3.6 Adverse events

Dogs:

Common (1 to 10 animals / 100 animals	Injection site swelling[1].

treated):	
Rare (1 to 10 animals / 10,000 animals treated):	Elevated temperature[2]. Hypersensitivity reaction (e.g. lethargy, facial oedema, pruritus, dyspnoea, vomiting, diarrhoea or collapse, including anaphylaxis)[2].

[1] Up to 5 mm in diameter. This swelling may be hard and painful and last for up to 3 days post injection.
[2] Transient.

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 in pregnant bitches which have previously been vaccinated with the CDV (strain Onderstepoort), CAV_2 (strain Manhattan LPV3) and CPV (strain 154) antigens included in the Nobivac vaccine range.

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 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.

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. 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 in the Nobivac range against infectious tracheobronchitis caused by *Bordetella bronchiseptica* and/or canine parainfluenza virus.

Safety and efficacy 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 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.

3.9 Administration routes and dosage

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 solvent provided or the vaccines in the Nobivac range against rabies or leptospirosis as mentioned in section 3.8 (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.

Reconstituted product: off-pink or pink coloured suspension.

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

No effects other than those given in section 3.6.

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

3.12 Withdrawal periods

Not applicable.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI07AD02.

The 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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product, except the solvent supplied or the vaccines in the Nobivac range mentioned in section 4.8 (where these products are authorised).

5.2 Shelf life

Lyophilisate: Shelf life of the veterinary medicinal product as packaged for sale: 24 months.
Solvent: Shelf life of the veterinary medicinal product as packaged for sale: 5 years.

Shelf life after reconstitution: 30 minutes.

5.3 Special precautions for storage

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

Solvent:
Store below 25 °C if stored separately from the lyophilisate.

5.4 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.

Pack sizes:
Cardboard or plastic box containing 10 or 50 single dose vials.
The 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 product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater.

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 International B.V.

7. MARKETING AUTHORISATION NUMBERS

Vm 06376/3036
Vm 06376/5034

8. DATE OF FIRST AUTHORISATION

28 July 2005

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

March 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

Gavin Hall
Approved: 11 August 2025