

PARTICULARS TO APPEAR ON THE OUTER PACKAGE {CARDBOAR OR PLASTIC BOX}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac DHP lyophilisate and solvent for suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose (1 ml) contains:

Canine distemper virus (strain Onderstepoort) $\geq 10^{4.0}$ TCID₅₀

Canine adenovirus 2 (strain Manhattan LPV3) $\geq 10^{4.0}$ TCID₅₀

Canine parvovirus (strain 154) $\geq 10^{7.0}$ TCID₅₀

3. PACKAGE SIZE

10 single dose vials of vaccine and/or solvent

50 single dose vials of vaccine and/or solvent

4. TARGET SPECIES

Dogs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Subcutaneous use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

Once reconstituted use within 30 minutes.

9. SPECIAL STORAGE PRECAUTIONS

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

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.

14. MARKETING AUTHORISATION NUMBERS

Vm 06376/3036

Vm 06376/5034

15. BATCH NUMBER

Lot {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING
UNITS {GLASS VIAL LABEL - Lyophilisate}**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac DHP



2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

CDV: $\geq 10^{4.0}$ TCID₅₀
CAV2: $\geq 10^{4.0}$ TCID₅₀
CPV: $\geq 10^{7.0}$ TCID₅₀

1 dose

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once reconstituted use within 30 min.

PARTICULARS TO APPEAR ON THE IMMEDIATE SOLVENT LABEL

GLASS VIAL - Solvent

1. NAME OF THE DILUENT/SOLVENT

Nobivac Solvent
– sterile buffered solution

2. CONTENT BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

1 dose

3. ROUTES OF ADMINISTRATION

Read package leaflet before use.

4. STORAGE CONDITIONS

Store below 25 °C.

5. BATCH NUMBER

Lot {number}

6. EXPIRY DATE

Exp. {mm/yyyy}

7. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V. logo

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Nobivac DHP lyophilisate and solvent for suspension for injection for dogs

2. Composition

Each dose (1 ml) of reconstituted vaccine contains:

Active substances:

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

*Tissue culture infective dose 50%

Lyophilisate: off-white or cream-coloured pellet.

Solvent: clear colourless solution.

3. Target species

Dogs.

4. Indications for use

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.

5. Contraindications

None.

6. Special warnings

Special warnings:

Vaccinate healthy animals only.

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.

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.

Pregnancy:

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 range.

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 ($\leq 1^{\circ}\text{C}$) 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.

Overdose:

No effects other than those given in “Adverse events” section.

Major incompatibilities:

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

7. Adverse events

Dogs:

Common (1 to 10 animals / 100 animals treated):	Injection site swelling ¹ .
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 product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at:

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

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 the 'Special warnings' section (where these products are authorised).

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.

9. Advice on correct administration

Sterile equipment should be used for administration.

Avoid contamination of vaccine with traces of chemical sterilising agents. Do not use chemicals such as disinfectants or spirit to disinfect the skin prior to inoculation.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

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.

Do not use this veterinary medicinal product after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

Shelf life after reconstitution: 30 minutes.

12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Vm 06376/3036

Vm 06376/5034

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.

15. PID link (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

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

16. Contact details

Marketing authorisation holder:

Intervet International B.V.

Wim de Körverstraat 35

5831 AN Boxmeer

Netherlands

Manufacturer responsible for batch release:

Intervet International B.V.

Wim de Körverstraat 35

5831 AN Boxmeer

Netherlands

Contact details to report suspected adverse reactions:

UK(GB)

MSD Animal Health UK Ltd.

Tel.: +44 (0)1908 685685

UK(NI)

Intervet Ireland Ltd.

Tel.: +353 (0)1 2970220

Local representative:

MSD Animal Health UK Limited

Walton Manor, Walton

Milton Keynes

MK7 7AJ

United Kingdom

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information

POM-V

Gavin Hall
Approved: 11 August 2025