LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac DHP

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Per dose of 1 ml:
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) $\geq 10^{7.0}$ $TCID_{50}$

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for injection

4. PACKAGE SIZE

10 or 50 single dose vials of vaccine and/or diluent.

5. TARGET SPECIES

Dogs

6. INDICATION(S)

Active immunisation of dogs against canine distemper, canine contagious hepatitis caused by canine adenovirus type 1, canine adenovirus type 2 and canine parvovirus.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous injection
Read the package leaflet before use for directions, warnings and disposal advice
[Comment: mentioned on the packaging item only once]

8. WITHDRAWAL PERIOD

Not applicable *[Comment: will not be mentioned on the packaging item]*

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use for directions, warnings and disposal advice.
[Comment: mentioned on the packaging item only once]

10. EXPIRY DATE

Exp {month/year}
Once reconstituted use within 30 minutes

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Read package leaflet before use for directions, warnings and disposal advice.
[Comment: mentioned on the packaging item only once]

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only - to be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF REACH AND SIGHT OF CHILDREN"

Keep out of reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Ltd.
Walton Manor
Walton
Milton Keynes
MK7 7AJ

16. MARKETING AUTHORISATION NUMBER

Vm 01708/4513

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac DHP

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

$\geq 10^{4.0}$ $TCID_{50}$ CDV
$\geq 10^{4.0}$ $TCID_{50}$ CAV2
$\geq 10^{7.0}$ $TCID_{50}$ CPV

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

1 dose

4. ROUTE OF ADMINISTRATION

s.c.

5. WITHDRAWAL PERIOD

Not applicable *[Comment: will not be mentioned on the packaging item]*

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}
Once reconstituted use within 30 min.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

Nobivac DHP

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing Authorisation Holder:
MSD Animal Health UK Ltd.
Walton Manor
Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

Manufacturer for batch release:
Intervet International B.V.
Wim de Körverstraat 35
NL- 5831 AN Boxmeer

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac DHP
Lyophilisate and solvent for suspension for injection

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Active substances:
Per dose of 1 ml 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 (1 ml per vial)*:*
Phosphate buffered saline.

4. INDICATION(S)

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: one week
Duration of immunity: three years.

5. CONTRAINDICATIONS

None

6. ADVERSE REACTIONS

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.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs

8. DOSAGE FOR EACH SPECIES, ROUTE(S) 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 diluent provided or the vaccines of the Nobivac series against rabies or leptospirosis as mentioned in section 12 (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.

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 PERIOD

Not applicable

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.
Store in a refrigerator (2 °C – 8 °C).
Do not freeze.
Protect from light.
Do not use after the expiry date stated on the label
Shelf-life after reconstitution: 30 minutes.

12. SPECIAL WARNING(S)

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.

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.

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.

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.

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.

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 of the Nobivac series against Bordetella bronchiseptica.

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.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIAL, IF ANY

Dispose of waste material by boiling, incineration or immersion in an appropriate disinfectant approved for use by the competent authorities.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED

15. OTHER INFORMATION

Cardboard box containing 10 or 50 single dose vials.
The diluent may be packed together with the vaccine or separately.
Not all pack sizes may be marketed.

Approved 25 February 2022