SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac DHPPi Vet. lyophilisate and solvent for suspension for injection for dogs.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 dose of 1 ml contains:

Active substances:

Live canine distemper virus (CDV) strain Onderstepoort	$\geq 10^{4.0}$ $TCID_{50}$*
Live canine adeno virus type 2 (CAV_2) strain Manhattan LPV3	$\geq 10^{4.0}$ $TCID_{50}$*
Live canine parvovirus (CPV) strain 154	$\geq 10^{7.0}$ $TCID_{50}$*
Live canine parainfluenza virus (CPi) strain Cornell	$\geq 10^{5.5}$ $TCID_{50}$*

* $TCID_{50}$ = median Tissue Culture Infective Dose

Solvent:
Phosphate buffered saline.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for injection.

Lyophilisate: off-white or cream-coloured pellet.
Solvent: clear colourless solution.
Reconstituted product: off-pink or pink coloured suspension.

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 prevent 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 and canine parainfluenza virus infection.

The onset of immunity is approximately one week after vaccination and lasts for three years for CDV, CAV_2 and CPV. Onset of immunity for CPi is approximately four weeks and lasts for one year after vaccination.

4.3 Contraindications

None.

4.4 Special warnings for each target species

None.

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 first 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 showing a copy of the product literature.

4.6 Adverse reactions (frequency and seriousness)

A small transient swelling at the site of injection (≤ 5 cm), which can occasionally be firm and painful on palpation, has been reported in very rare cases. Any such swelling will either have disappeared or be clearly diminished by 14 days post-vaccination.
A transient rise in body temperature has been observed after vaccination in very rare cases.
A transient acute hypersensitivity reaction - with signs that may include lethargy, facial oedema, pruritus, vomiting or diarrhoea - may occur shortly after vaccination in very rare cases. Such reaction may evolve to a more severe condition (anaphylaxis), which may be life-threatening with additional signs like ataxia, dyspnea, tremor and collapse. If such reactions occur, appropriate treatment is recommended.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reactions)
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay

Can be used during pregnancy.
No data is available on the safety in lactating bitches.

4.8 Interaction with other medicinal products and other forms of interaction

Safety and efficacy data (viral excretion) 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.

The product information of the relevant Nobivac vaccines should be consulted before administration of the mixed product. 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.

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.

No information is available on the compatibility 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

One ml solvent or 1 ml (1 dose) of inactivated vaccine (as specified in section 4.8) must be used to reconstitute the freeze-dried Nobivac DHPPi vaccine.
One dose (1 ml) of reconstituted vaccine should be given by subcutaneous injection.

Vaccination program:
Basic 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.

Revaccination: Every year for CPi, and every third year for CPV, CDV and CAV_2.

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

No particular signs at 10-fold overdose.

4.11 Withdrawal period(s)

Not applicable.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: live viral vaccine for dogs.
ATCvet code: QI07AD04.

The vaccine stimulates active immunity in dogs against canine distemper, contagious hepatitis (CAV1), canine adenovirus infection (CAV2), canine parvovirus (CPV) infection and canine parainfluenza (CPi) infection.
The recommend vaccination will induce a protective titre in almost all vaccinated dogs.
Immunity is also accomplished in animals with maternal antibodies present at the time of vaccination.
From some dogs CPV may be found in faeces for up to 8 days after vaccination. Occasionally the virus spreads to other dogs, but without causing clinical symptoms of disease. For CPi a protective antibody titre is not accomplished in all vaccinated dogs, but reduction of clinical signs has been shown.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

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

6.2 Incompatibilities

Do not mix with any other veterinary medicinal products, except the solvent supplied with the product or other Nobivac dog vaccines 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 according to directions: 30 minutes.

6.4. Special precautions for storage

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

Solvent:
Store below 25°C if stored independently from the vaccine.

6.5 Nature and composition of immediate packaging

Vaccine:
Vial of hydrolytical class type I (Ph.Eur.) glass closed with a halogenobutyl rubber stopper and a colour coded aluminium cap.

Solvent:
Vial of hydrolytical class type I (Ph.Eur.) glass closed with a halogenobutyl rubber stopper and a colour coded aluminium cap.

Pack sizes: Carton or plastic box with 5, 10, 25 or 50 single dose vials.
Solvent may be packed together with the vaccine or separately.
Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product 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 International B.V.
Wim de Korverstraat 35
5831 AN Boxmeer
The Netherlands

represented by the national companies

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: {DD/MM/YYYY}
Date of last renewal: {DD/MM/YYYY}

10 DATE OF REVISION OF THE TEXT

{MM/YYYY}

PROHIBITION OF SALE, SUPPLY AND/OR USE

Veterinary medicinal product subject to prescription.

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton or plastic box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac DHPPi Vet.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Per dose of 1 ml:

Live canine distemper virus (CDV) strain Onderstepoort	$\geq 10^{4.0}$ $TCID_{50}$
Live canine adeno virus type 2 (CAV_2) strain Manhattan LPV3	$\geq 10^{4.0}$ $TCID_{50}$
Live canine parvovirus (CPV) strain 154	$\geq 10^{7.0}$ $TCID_{50}$
Live canine parainfluenza virus (CPi) strain Cornell	$\geq 10^{5.5}$ $TCID_{50}$

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for injection.

4. PACKAGE SIZE

5x 1 dose
10x 1 dose
25x 1 dose
50x 1 dose

5. TARGET SPECIES

Dogs.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous use.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

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

11. SPECIAL STORAGE CONDITIONS

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

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

Read the package leaflet before use.

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 THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

The national representative of
Intervet International B.V.
Wim de Körverstraat 35
NL - 5831 AN BOXMEER

16. MARKETING AUTHORISATION NUMBER(S)

{national number}

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac DHPPi Vet.

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

$\geq 10^{4.0}$ $TCID_{50}$ live CDV
$\geq 10^{4.0}$ $TCID_{50}$ live CAV_2
$\geq 10^{7.0}$ $TCID_{50}$ live CPV
$\geq 10^{5.5}$ $TCID_{50}$ live CPi

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

1 dose.

4. ROUTE(S) OF ADMINISTRATION

SC

5. WITHDRAWAL PERIOD

Not applicable

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

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

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

Nobivac DHPPi Vet. lyophilisate and solvent for suspension for injection for dogs.

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

Marketing authorization holder:
The national representative of
Intervet International B.V.
Wim de Körverstraat 35
NL - 5831AN Boxmeer

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac DHPPi Vet. lyophilisate and solvent for suspension for injection for dogs.

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

1 dose of 1 ml contains:

Active substances:

Live canine distemper virus (CDV) strain Onderstepoort	$\geq 10^{4.0}$ $TCID_{50}$*
Live canine adeno virus type 2 (CAV_2) strain Manhattan LPV3	$\geq 10^{4.0}$ $TCID_{50}$*
Live canine parvovirus (CPV) strain 154	$\geq 10^{7.0}$ $TCID_{50}$*
Live canine parainfluenza virus (CPi) strain Cornell	$\geq 10^{5.5}$ $TCID_{50}$*

* $TCID_{50}$ = median Tissue Culture Infective Dose

Solvent:
Phosphate buffered saline.

Lyophilisate: off-white or cream-coloured pellet.
Solvent: clear colourless solution.
Reconstituted product: off-pink or pink coloured suspension.

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 prevent 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 and canine parainfluenza virus infection.

The onset of immunity is approximately one week after vaccination and lasts for three years for CDV, CAV_2 and CPV. Onset of immunity for CPi is approximately four weeks and lasts for one year after vaccination.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

A small transient swelling at the site of injection (≤ 5 cm), which can occasionally be firm and painful on palpation, has been reported in very rare cases. Any such swelling will either have disappeared or be clearly diminished by 14 days post-vaccination.
A transient rise in body temperature has been observed after vaccination in very rare cases.
A transient acute hypersensitivity reaction - with signs that may include lethargy, facial oedema, pruritus, vomiting or diarrhoea - may occur shortly after vaccination in very rare cases. Such reaction may evolve to a more severe condition (anaphylaxis), which may be life-threatening with additional signs like ataxia, dyspnea, tremor and collapse. If such reactions occur, appropriate treatment is recommended.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reactions)
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

If you notice any side effects, even those already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

One ml solvent or 1 ml (1 dose) of inactivated vaccine (as specified in section 4.8) must be used to reconstitute the freeze-dried Nobivac DHPPi vaccine.
One dose (1 ml) of reconstituted vaccine should be given by subcutaneous injection.

Vaccination program:
Basic 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.

Revaccination: Every year for CPi, and every third year for CPV, CDV and CAV_2.

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Vaccine: Store in a refrigerator (2°C - 8°C). Do not freeze. Protect from light.
Solvent: Store below 25°C if stored independently from the vaccine.

Do not use this veterinary medicinal product after the expiry date which is stated on the label.

Shelf-life after reconstitution according to directions: 30 minutes.

12. SPECIAL WARNING(S)

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 first 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 showing a copy of the product literature.

Pregnancy:
Can be used during pregnancy.
No data is available on the safety in lactating bitches.

Interaction with other medicinal products and other forms of interaction:

For the veterinarian only:

Safety and efficacy data (viral excretion) 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.

The product information of the relevant Nobivac vaccines should be consulted before administration of the mixed product. 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.

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.

No information is available on the compatibility 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 (symptoms, emergency procedures, antidotes):
No particular signs at 10-fold overdose.

Incompatibilities:
Do not mix with any other veterinary medicinal products, except the solvent supplied with the product or other Nobivac dog vaccines mentioned above (where these products are authorised).

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 APPROVED

15. OTHER INFORMATION

Pack sizes: Carton or plastic box with 5, 10, 25 or 50 single dose vials.
Solvent may be packed together with the vaccine or separately.
Not all pack sizes may be marketed.

Veterinary medicinal product subject to prescription.