ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac DP PLUS lyophilisate and solvent for suspension for injection for dogs (puppies)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (1 ml) of reconstituted vaccine contains:

Active substances:
Live attenuated canine distemper virus strain Onderstepoort: $10^{5.1}$ – $10^{6.5}$ $TCID_{50}$*
Live recombinant canine parvovirus strain 630a: $10^{5.1}$ – $10^{6.7}$ $TCID_{50}$*

* Tissue culture infective dose 50%

Excipients:

Qualitative composition of excipients and other constituents
Lyophilisate:
Hydrolysed gelatine
Pancreatic digest of casein
Sorbitol
Disodium phosphate dihydrate
Solvent:
Disodium phosphate dihydrate
Potassium dihydrogen phosphate
Water for injections

Lyophilisate: off-white or cream-colour.
Solvent: clear colourless solution.

3. CLINICAL INFORMATION

3.1 Target species

Dogs (puppies).

3.2 Indications for use for each target species

For the active immunisation of puppies from 4 weeks of age onwards to prevent clinical signs and mortality of canine distemper virus infection and canine parvovirus infection and to prevent viral excretion following canine distemper virus infection and following canine parvovirus infection.

Onset of immunity: for canine distemper virus: 7 days;
for canine parvovirus: 3 days.

Duration of immunity: 8 weeks.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Moderate to high levels of maternally derived antibodies against canine distemper virus can reduce the efficacy of the product against canine distemper.

It is typically advised that each pup is vaccinated with this product at 6 weeks of age. In cases where there is a high risk of canine parvovirus infection and/or canine distemper virus infection, it is advised that pups are vaccinated earlier, but not before 4 weeks of age. The routine vaccinations with core vaccines against canine distemper, canine parvovirosis, canine contagious hepatitis and respiratory disease caused by adenovirus type 2 infection should be given as indicated in the package leaflets of these products.

In some puppies, the canine parvovirus vaccine strain may be found in faeces for up to 8 days after vaccination. Occasionally this virus can spread to other dogs or cats, but without causing clinical signs of disease. In cats, the virus may be shed up to 5 days and spread to other cats without causing any signs of disease. Canine distemper virus is not spread by vaccinated puppies.

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.

3.6 Adverse events

Dogs:

Very common (>1 animal / 10 animals treated):	Injection site swelling[1].
Rare (1 to 10 animals / 10,000 animals treated):	Lethargy[2].
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersensitivity reaction[3].

[1] Small, non-painful swelling (≤ 1 cm diameter) within the first week after vaccination. The swelling will resolve completely within a few days.
[2] Within 4 hours after vaccination.
[3] Including anaphylaxis (sometimes fatal). If such a reaction occurs, appropriate treatment should be administered without delay.

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

The safety of the veterinary medicinal product has not been established during pregnancy.

3.8 Interaction with other medicinal products and other forms of interaction

Safety data are available which demonstrate that this vaccine can be administered on the same day but not mixed with vaccine of the Nobivac series containing *Bordetella bronchiseptica* and canine parainfluenza virus components for intranasal administration. Efficacy after concurrent use has not been tested. Therefore, while safety of concurrent use has been demonstrated, the veterinarian should take this into account when deciding to administer the products at the same time.

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except the one 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

Subcutaneous use.

Administer one dose (1 ml) to puppies from 4 weeks of age onwards.
Reconstitute the vial containing the lyophilisate with the supplied solvent.
Ensure that the lyophilisate is completely reconstituted before use.
Administer the total contents of the vial.

Reconstituted product: off-pink or pink coloured suspension.

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

No adverse reactions other than those mentioned in section 3.6 were observed after administration of a 10-fold overdose of the vaccine.

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

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI07AD03.

The vaccine stimulates active immunity in puppies against canine parvovirus and canine distemper virus infection. Maternally derived antibodies against canine parvovirus do not interfere with the efficacy of this product. Immunity against canine distemper virus is achieved in animals of 4 weeks of age with low to moderate levels of maternal antibodies.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product, except the solvent supplied for use with the veterinary medicinal product.

5.2 Shelf life

Shelf life of the veterinary medicinal product (lyophilisate) as packaged for sale: 2 years.
Shelf life of the solvent as packaged for sale: 4 years.
Shelf life after reconstitution according to directions: 30 minutes.

5.3 Special precautions for storage

Lyophilisate:
Store in a refrigerator (2 °C – 8 °C).
Do not transport above 30 °C.
Do not freeze.
Protect from light.

Solvent:
No special precautions for storage.

5.4 Nature and composition of immediate packaging

Lyophilisate:
Type I clear glass vial of 1 dose closed with a chlorobutyl rubber stopper and aluminium cap.

Solvent:
Type I clear glass vial of 1 ml closed with a bromobutyl rubber stopper and aluminium cap.

Pack sizes:
- Plastic box with 5 x 1 dose vial of vaccine and 5 vials containing 1 ml of solvent.
- Plastic box with 25 x 1 dose vial of vaccine and 25 vials containing 1 ml of solvent.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

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 NUMBER(S)

EU/2/20/265/001-002

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 09/12/2020.

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

{MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

ANNEX II

OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

None

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

BOX
Plastic box with 5 x 1 dose vial of vaccine and 5 x 1 ml vial of solvent
Plastic box with 25 x 1 dose vial of vaccine and 25 x 1 ml vial of solvent

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac DP PLUS lyophilisate and solvent for suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose (1 ml) contains:
Live attenuated canine distemper virus strain Onderstepoort: $10^{5.1}$ – $10^{6.5}$ $TCID_{50}$
Live recombinant canine parvovirus strain 630a: $10^{5.1}$ – $10^{6.7}$ $TCID_{50}$

3. PACKAGE SIZE

5 x 1 dose of vaccine including 1 ml solvent
25 x 1 dose of vaccine including 1 ml solvent

4. TARGET SPECIES

Dogs (puppies)

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 transport above 30 ºC.
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

EU/2/20/265/001 (5 x 1 dose; 5 x 1 ml)
EU/2/20/265/002 (25 x 1 dose; 25 x 1 ml)

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

VACCINE VIAL LABEL (LYOPHILISATE - 1 dose)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac DP PLUS 

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

1 dose
Live attenuated canine distemper virus
Live recombinant canine parvovirus

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

SOLVENT VIAL LABEL (1 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Solvent for Nobivac DP PLUS 

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

1 dose

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Nobivac DP PLUS lyophilisate and solvent for suspension for injection for dogs (puppies)

2. Composition

Each dose (1 ml) of reconstituted vaccine contains:

Active substances:
Live attenuated canine distemper virus strain Onderstepoort: $10^{5.1} – 10^{6.5}$ $TCID_{50}$*
Live recombinant canine parvovirus strain 630a: $10^{5.1} – 10^{6.7}$ $TCID_{50}$*

* Tissue culture infective dose 50%

Lyophilisate: off-white or cream-colour.
Solvent: clear colourless solution.

3. Target species

Dogs (puppies).

4. Indications for use

For the active immunisation of puppies from 4 weeks of age onwards to prevent clinical signs and mortality of canine distemper virus infection and canine parvovirus infection and to prevent viral excretion following canine distemper virus infection and following canine parvovirus infection.

Onset of immunity: for canine distemper virus: 7 days;
for canine parvovirus: 3 days.

Duration of immunity: 8 weeks.

5. Contraindications

None.

6. Special warnings

Special warnings:
Vaccinate healthy animals only.

Special precautions for safe use in the target species:
Moderate to high levels of maternally derived antibodies against canine distemper virus can reduce the efficacy of the product against canine distemper.

It is typically advised that each pup is vaccinated with this product at 6 weeks of age. In cases where there is a high risk of canine parvovirus infection and/or canine distemper virus infection, it is advised that pups are vaccinated earlier, but not before 4 weeks of age. The routine vaccinations with core vaccines against canine distemper, canine parvovirosis, canine contagious hepatitis and respiratory

disease caused by adenovirus type 2 infection should be given as indicated in the package leaflets of these products.

In some puppies the canine parvovirus vaccine strain may be found in faeces for up to 8 days after vaccination. Occasionally this virus can spread to other dogs or cats, but without causing clinical signs of disease. In cats the virus may be shed up to 5 days and spread to other cats without causing any signs of disease. Canine distemper virus is not spread by vaccinated puppies.

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:
The safety of the veterinary medicinal product has not been established during pregnancy.

Interaction with other medicinal products and other forms of interaction:
Safety data are available which demonstrate that this vaccine can be administered on the same day but not mixed with vaccine of the Nobivac series containing *Bordetella bronchiseptica* and parainfluenza virus components for intranasal administration. Efficacy after concurrent use has not been tested. Therefore, while safety of concurrent use has been demonstrated, the veterinarian should take this into account when deciding to administer the products at the same time.

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product. 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 adverse reactions other than those mentioned in section "Adverse Events" were observed after administration of a 10-fold overdose of the vaccine.

Major incompatibilities:
Do not mix with any other veterinary medicinal product, except solvent supplied for use with the veterinary medicinal product.

7. Adverse events

Dogs:

Very common (>1 animal / 10 animals treated):	Injection site swelling[1].
Rare (1 to 10 animals / 10,000 animals treated):	Lethargy[2].
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersensitivity reaction[3].

[1] Small, non-painful swelling (≤ 1 cm diameter) within the first week after vaccination. The swelling will resolve completely within a few days.
[2] Within 4 hours after vaccination.
[3] Including anaphylaxis (sometimes fatal). If such a reaction occurs, appropriate treatment should be administered without delay.

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 using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

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

Subcutaneous use.

Administer one dose (1 ml) to puppies from 4 weeks of age onwards.
Reconstitute the vial containing the lyophilisate with the supplied solvent.
Administer the total contents of the vial.

Reconstituted product: off-pink or pink coloured suspension.

9. Advice on correct administration

Ensure that the lyophilisate is completely reconstituted before use.

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 transport above 30 °C. Do not freeze. Protect from light.
Solvent: This veterinary medicinal product does not require any special temperature storage conditions.

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 according to directions: 30 minutes.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

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.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

EU/2/20/265/001-002

Pack sizes:
- Plastic box with 5 x 1 dose vial of vaccine and 5 vials containing 1 ml of solvent.
- Plastic box with 25 x 1 dose vial of vaccine and 25 vials containing 1 ml of solvent.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{MM/YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:
Intervet International B.V., Wim de Körverstraat 35, 5831 AN Boxmeer, The Netherlands

België/Belgique/Belgien
Tél/Tel: + 32 (0)2 370 94 01

Република България
Тел: + 359 28193749

Česká republika
Tel: + 420 233 010 242

Danmark
Tlf: + 45 44 82 42 00

Deutschland
Tel: + 49 (0)8945614100

Eesti
Tel: + 37052196111

Ελλάδα
Τηλ: + 30 210 989 7452

España
Tel: + 34 923 19 03 45

France
Tél: + 33 (0)241228383

Hrvatska
Tel: + 385 1 6611339

Ireland
Tel: + 353 (0) 1 2970220

Lietuva
Tel: + 37052196111

Luxembourg/Luxemburg
Tél/Tel: + 32 (0)2 370 94 01

Magyarország
Tel.: + 36 1 439 4597

Malta
Tel: + 39 02 516861

Nederland
Tel: + 32 (0)2 370 94 01

Norge
Tlf: + 47 55 54 37 35

Österreich
Tel: + 43 (1) 256 87 87

Polska
Tel.: + 48 22 18 32 200

Portugal
Tel: + 351 214 465 700

România
Tel: + 40 21 311 83 11

Slovenija
Tel: + 385 1 6611339

Ísland
Sími: + 354 535 7000

Italia
Tel: + 39 02 516861

Κύπρος
Τηλ: + 30 210 989 7452

Latvija
Tel: + 37052196111

Slovenská republika
Tel: + 420 233 010 242

Suomi/Finland
Puh/Tel: + 358 10 2310 750

Sverige
Tel: + 46 (0)8 522 216 60

United Kingdom (Northern Ireland)
Tel: + 353 (0) 1 2970220

17. Other information

The vaccine stimulates active immunity in puppies against canine parvovirus and canine distemper virus infection. Maternally derived antibodies against canine parvovirus do not interfere with the efficacy of this product. Immunity against canine distemper virus is achieved in animals of 4 weeks of age with low to moderate levels of maternal antibodies.