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%

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-colour.
Solvent: clear colourless solution.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs (puppies).

4.2 Indications for use, specifying the 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.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Vaccinate healthy animals only.

4.5 Special precautions for use

Special precautions for use in animals:
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.

4.6 Adverse reactions (frequency and seriousness)

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] **I**ncluding 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 also section 16 of the package leaflet for contact details.

4.7 Use during pregnancy, lactation or lay

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

4.8 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.

4.9 Amount(s) to be administered and administration route

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.

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

No adverse reactions other than those mentioned in section 4.6 were observed after administration of a 10-fold overdose of the vaccine.

4.11 Withdrawal period(s)

Not applicable.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: live viral vaccine for dogs, canine distemper virus and canine parvovirus.

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lyophilisate:
Hydrolysed gelatine
Pancreatic digest of casein
Sorbitol
Disodium phosphate dihydrate

Solvent:
Disodium phosphate dihydrate
Potassium dihydrogen phosphate
Water for injections

6.2 Major incompatibilities

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

6.3 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.

6.4 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.

6.5 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.

6.6 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.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Limited
Walton Manor, Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

8. MARKETING AUTHORISATION NUMBER

Vm 01708/5047

9. DATE OF FIRST AUTHORISATION

09 December 2020

10. DATE OF REVISION OF THE TEXT

November 2023

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

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

Approved 17 November 2023