1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac Parvo-C lyophilisate and solvent for suspension for injection for dogs.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml dose of reconstituted vaccine contains:

Active substances:
Canine parvovirus, strain 154, live $\geq 10^{7.0}$ $TCID_{50}$*
*Tissue culture infective dose 50%

Excipients:

Qualitative composition of excipients and other constituents
Lyophilisate:
Sorbitol
Gelatin
Pancreatic digest of casein
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.

3.2 Indications for use for each target species

For active immunisation of dogs to prevent clinical signs of disease and excretion of virulent canine parvovirus caused by canine parvovirus infection.
Onset of immunity: 1 week.

Duration of immunity: up to 3 years.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

The efficacy 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 that are likely to be encountered under field conditions.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Dogs should not be exposed to unnecessary risk of infection within the first week after vaccination. 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, wash the area with water and 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:

Common (1 to 10 animals / 100 animals treated):	Injection site swelling[1,2]
Rare (1 to 10 animals / 10 000 animals treated):	Elevated temperature[2], Hypersensitivity reaction[2] (e.g. Lethargy, Facial oedema, Pruritus, Dyspnoea, Vomiting, Diarrhoea, Collapse, Anaphylaxis).

[1] After subcutaneous administration with the solvent provided. Diffuse, up to 5 mm in diameter. Can be hard and painful, for up to 3 days post injection.
[2] Transient, shortly after vaccination.

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 its local representative 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

Pregnancy:
Can be used during pregnancy in bitches that have previously been vaccinated with the CPV (strain 154) antigen included in the Nobivac vaccine range.

3.8 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 (≤ 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 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 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.

3.9 Administration routes and dosage

Subcutaneous use.

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 ml) of the solvent provided or the vaccines of the Nobivac range against rabies or leptospirosis as mentioned in section 3.8 (where these products are authorised).

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.

<u>Regimen of vaccination</u>

Basic vaccination scheme
A single injection should establish active immunity to diseases caused by canine parvovirus 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 antibodies 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.

Re-vaccination scheme.
To maintain protection a single booster dose is recommended every three years.

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

No effects other than those given in section 3.6.

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 : QI07AD01.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product, except with the solvent provided or the vaccines of the Nobivac range mentioned in section 3.8 (where these products are authorised).

5.2 Shelf life

Lyophilisate: Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Solvent: Shelf life of the veterinary medicinal product as packaged for sale: 5 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 freeze.
Protect from light.

Solvent:
Store below 25 °C if stored separately from the lyophilisate.

5.4 Nature and composition of immediate packaging

Lyophilisate:
Clear, Glass Type I (Ph.Eur.) vials of 1 ml closed with a halogenobutyl rubber stopper and sealed with a colour coded aluminium cap.

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

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.

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 Ireland Limited

7. MARKETING AUTHORISATION NUMBER(S)

VPA10996/167/001

8. DATE OF FIRST AUTHORISATION

05/03/2004

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

08/12/2025

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).