SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac Parvo-C Lyophilisate for Suspension for Injection for Dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml dose of reconstituted vaccine contains:

Active substance:
Canine parvovirus (CPV), strain 154, live ≥ $10^{7.0}$ $TCID_{50}$*
*Tissue culture infective dose 50%

Excipients:

Qualitative composition of excipients and other constituents
Sorbitol
Hydrolysed gelatin
Pancreatic digest of casein
Disodium phosphate dihydrate
Water for injections

Lyophilisate: off-white or cream-coloured pellet.

3. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each target species

For active immunisation of dogs to prevent mortality, clinical signs and viral excretion following canine parvovirus infection.

Onset of immunity: 1 week.
Duration of immunity: 3 years.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

The vaccine may not be effective in dogs incubating the disease at the time of vaccination.

A good immune response is reliant on the reaction of an immunogenic agent and a fully competent immune system. Immunocompetence of the animal may be compromised by a variety of factors including poor health, nutritional status, genetic factors, concurrent drug therapy and stress.

The immunogenicity of the vaccine antigen will be reduced by poor storage or inappropriate administration.

The vaccine has been proved to be of benefit against virulent challenge in the presence of maternal antibody levels to CPV that are likely to be encountered under field conditions.

Experience has shown that the maternal antibody status of pups within a litter varies greatly, and reliance should not be placed on serological examination of the bitch alone.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Animals that have received a corresponding anti-serum or immunosuppressive drugs should not be vaccinated until an interval of at least 4 weeks has elapsed.

Vaccinated dogs may excrete the parvovirus vaccine strain at very low levels for up to 8 days after vaccination. However, there is no evidence of any reversion to virulence of the vaccine strain and therefore no need to separate unvaccinated dogs from contact with recently vaccinated dogs.

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:

Common (1 to 10 animals / 100 animals treated):	Injection site swelling[1,2]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersensitivity reaction (e.g. lethargy, facial oedema, pruritus, vomiting or diarrhoea)[2,3]

[1] Diffuse, up to 5 mm in diameter, which can occasionally be hard and painful and can last for up to 3 days post injection.
[2] Transient, shortly after vaccination.
[3] Such reaction may evolve to a more severe condition (anaphylaxis), which may be life-threatening with additional signs like dyspnoea and collapse. If such reaction occurs, appropriate treatment is recommended.

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.
Pregnant bitches should have been previously 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-vaccination.

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 range against *Bordetella bronchiseptica*.

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

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.

Reconstitute the vaccine with 1 ml solvent or 1 ml (1 dose) of the inactivated vaccines listed in section 3.8.

Avoid contamination of vaccine with traces of chemical sterilising agents. Do not use chemicals such as disinfectant or spirit to disinfect the skin prior to administration.

Maternal antibodies can negatively interfere with the efficacy of a vaccine. Strict adherence to the vaccination programme is therefore recommended.

Vaccination programme:
Primary vaccination:
A single injection should establish active immunity to disease caused by canine parvovirus infection in dogs of 10 weeks of age or older. Where earlier protection is required a first dose may be given to puppies from 4 weeks of age, but because maternally derived passive antibodies can interfere with the response to vaccination, a final dose at 10 weeks of age or older is generally recommended.

Revaccination:
It is recommended that dogs be revaccinated against canine parvovirus every 3 years.

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

No clinical signs other than those indicated in section 3.6. In some dogs the swelling may be more painful or may be observed for a longer period.

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

The vaccine contains attenuated antigens to stimulate active immunity against canine parvovirus disease.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product except solvent supplied for use with the veterinary medicinal product or the Nobivac dog vaccines mentioned in section 3.8.

5.2 Shelf life

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

5.3 Special precautions for storage

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

Avoid prolonged or repetitive exposure to high ambient temperatures following withdrawal from the refrigerator prior to use. In hot summer conditions vaccine potency can be severely reduced within a few hours.

5.4 Nature and composition of immediate packaging

Type I (Ph. Eur.) clear glass single-dose vial with a halogenobutyl rubber stopper, sealed with a colour-coded aluminium cap.

Pack sizes:
Cardboard or plastic box containing 10 or 50 vials.

Not all pack sizes may be marketed

5.5 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 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

Vm 06376/4105

8. DATE OF FIRST AUTHORISATION

24 October 2005

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

February 2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

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

Gavin Hall
Approved: 26 February 2026