Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac Parvo-C

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each single dose of the vaccine vial contains:
Active Ingredients:
Canine parvovirus (strain 154) not less than $10^{7.0}$ $TCID_{50}$*

*Tissue culture infective dose 50%

Excipients:
For a full list of excipients see 6.1

Solvent (1ml per vial):
Phosphate buffered saline.

3 PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for injection.

4 CLINICAL PARTICULARS

4.1 Target Species

Dogs.

4.2 Indications for use, specifying the 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 has been shown to occur from 1 week after dosing and last for up to 3 years.

4.3 Contraindications

None.

4.4 Special warnings for each target species

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.

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 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 the case of accidental self-injection, wash the area immediately with water. If symptoms develop, seek medical advice immediately and show the package leaflet or the label to the physician.

4.6 Adverse reactions (frequency and seriousness)

A common reaction after subcutaneous administration with the diluent provided is a diffuse swelling up to 5 mm in diameter at the site of injection. Occasionally this swelling may be hard and painful and last for up to 3 days post injection.
In rare cases a transient rise in body temperature and/or a transient acute hypersensitivity reaction (anaphylaxis) - with signs that may include lethargy, facial oedema, pruritus, dyspnoea, vomiting, diarrhoea or collapse - may occur shortly after vaccination.

4.7 Use during pregnancy, lactation or lay

Can be used in pregnant bitches which have previously been vaccinated with the CPV (strain 154) antigen included in the Nobivac vaccine series.

4.8 Interaction with other medicinal products and other forms of interactions

Safety and efficacy data 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.

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 Parvo-C 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.

Safety and efficacy data are available which demonstrate that this vaccine can be mixed and administered with the inactivated vaccine of the Nobivac series 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 at the same time but not mixed with the inactivated vaccine of the Nobivac series against *Bordetella bronchiseptica*.

When Nobivac Parvo-C 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.

4.9 Amounts to be administered and administration route

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 (1.0ml) of the diluent providedor the vaccines of the Nobivac series against rabies or leptospirosis as mentioned in section 4.8 (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.

Regimen of Vaccination

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.

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

No effects other than those given in section 4.6.

4.11 Withdrawal period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

ATCvet code: QI07AD01The vaccine contains attenuated live virus to stimulate active immunity in dogs against canine parvovirus.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Gelatin
Sorbitol
Pancreatic digest of casein
Disodium phosphate dihydrate
Potassium dihydrogen phosphate
Water for injections.

6.2 Major incompatibilities

Do not mix with any other medicinal product except with the diluent provided or the vaccines of the Nobivac series 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: 30 minutes

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Clear, Glass Type I (Ph.Eur) single vials with halogenobutyl rubber stopper, closed with a colour coded aluminium cap. Cardboard or plastic box containing 10 or 50 single dose vials. The diluent 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 products 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 Ireland Limited
Magna Drive
Magna Business Park, Citywest Road
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA10996/167/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 05 March 2004
Date of last renewal: 05 March 2009

10 DATE OF REVISION OF THE TEXT

October 2021