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

Active ingredients:	per dose of 1 ml
Canine parvovirus	not less than $10^{7.0}$ $TCID_{50}$*

*Tissue culture infective dose 50%

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Lyophilisate for suspension for injection.
Lyophilisate: off-white or cream-coloured pellet.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs.

4.2 Indications for use, including target species

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

Specific claims:
An onset of immunity to the canine parvovirus vaccine component of 1 week has been demonstrated following use of the vaccine.
A duration of immunity of at least three years has been established for the canine parvovirus vaccine component.

4.3 Contraindications

Do not use in unhealthy animals. The vaccine may not be effective in dogs incubating the disease at the time of vaccination.
Some animals may be immunologically incompetent and fail to respond to vaccination. Animals that have received the corresponding anti-serum or immunosuppressive drugs should not be vaccinated until an interval of at least 4 weeks has elapsed.

4.4 Specific warnings for each target species

The efficacy of the CPV component of the vaccine may be reduced due to maternal antibody interference. However, 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.

4.5 Special precautions for use, including special precautions to be taken by the person administering the medicinal product to animals

Special precautions for use in animals
Only healthy dogs should be vaccinated.
The canine parvovirus vaccine strain may be shed at very low levels for up to 8 days after inoculation. 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 individuals.

Special precautions to be taken by the person administering the medicinal product to animals
None.

4.6 Adverse reactions (frequency and seriousness)

A diffuse swelling, up to 5 mm in diameter, may be observed at the site of injection. Occasionally this swelling may be hard and painful and last for up to 3 days post injection.
In the rare event of a hypersensitivity reaction occurring following vaccination, administer an antihistamine, corticosteroid or adrenaline, without delay and by the most immediate route.

4.7 Use during pregnancy and lactation

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

4.8 Interaction with other medicaments 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 of the Nobivac series for subcutaneous administration 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.
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 ml) of the diluent provided or the vaccines of the Nobivac series against rabies or leptospirosis as mentioned in section "Interactions".
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 inoculation.

Primary course 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 antibody can interfere with the response to vaccination a final dose at 10 weeks of age or older is generally recommended.

Booster vaccination:
It is recommended that dogs be revaccinated with canine parvovirus every 3 years.

Further information
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.
A good immune response is reliant on the reaction of an immunogenic agent and a fully competent immune system. The immunogenicity of the vaccine antigen will be reduced by poor storage or inappropriate administration. Immunocompetence of the animal may be compromised by a variety of factors including poor health, nutritional status, genetic factors, concurrent drug therapy and stress.

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

Similar in nature to that from a single dose (please see section 4.6). In some dogs the swelling may be more painful or may be observed for a longer period.

4.11 Withdrawal period

Not applicable.

5. IMMUNOLOGICAL PROPERTIES

ATCVet Code: QI07AD01

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

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sorbitol
Hydrolised Gelatine
Pancreatic digest of casein
Di-Sodium phosphate 12 H2O
Water for injections.

6.2 Incompatibilities

Do not mix with any other veterinary medicinal product except the diluent Nobivac Solvent, Nobivac Lepto 2, Nobivac L4 or Nobivac Rabies recommended for use with this product.

6.3 Shelf life

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

6.4 Special precautions for storage

Store in a refrigerator (2 °C - 8 °C). Do not freeze. Protect from light.
Care should be taken to 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.

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.
Cartons or plastic boxes containing 10 or 50 vials.
Not all presentations may be marketed.

6.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate

Dispose of waste material by boiling, incineration or immersion in an appropriate disinfectant approved for use by the competent authorities.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

Vm 01708/4361

9. DATE OF FIRST AUTHORISATION

24 October 2005

10. DATE OF REVISION OF THE TEXT

November 2020

Approved: 05 November 2020