PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard or plastic (PET) box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac Parvo-C lyophilisate for suspension for injection for dogs

2. STATEMENT OF ACTIVE SUBSTANCES

Each 1 ml dose contains:
Live canine parvovirus (CPV), strain 154 ≥ $10^{7.0}$ $TCID_{50}$

3. PHARMACEUTICAL FORM

Lyophilisate for suspension for injection.

4. PACKAGE SIZE

10 x 1 dose
50 x 1 dose

5. TARGET SPECIES

Dogs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous use.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP: {month/year}

Once reconstituted use within 30 minutes.

11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator.
Do not freeze.
Protect from light.
Keep the vials in the outer box.

Care should be taken to avoid prolonged and repetitive exposure to high ambient temperature.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

For animal treatment only.

POM-V
To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MA holder:
MSD Animal Health UK Ltd.
Walton Manor, Walton
Milton Keynes
MK7 7AJ

Distributor in Northern Ireland
Intervet Ireland Ltd.
Magna Drive
Magna Business Park
Citywest Road
Dublin 24

16. MARKETING AUTHORISATION NUMBER

Vm 01708/4361

17. MANUFACTURER'S BATCH NUMBER

Lot: {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS
Label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac Parvo-C 

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each 1 ml dose contains: Live CPV ≥ $10^{7.0}$ $TCID_{50}$

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

1 dose

4. ROUTE(S) OF ADMINISTRATION

SC

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Lot: {number}

7. EXPIRY DATE

EXP: {month/year}

Once reconstituted use within 30 minutes.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

Additional text
Keep the vial in the box.
POM-V
Vm 01708/4361

PACKAGE LEAFLET
Nobivac Parvo-C lyophilisate for suspension for injection for dogs

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
MSD Animal Health UK Ltd.
Walton Manor, Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

Manufacturer responsible for batch release:
Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac Parvo-C lyophilisate for suspension for injection for dogs

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

Each 1 ml dose contains:
Active substance:
Live canine parvovirus (CPV), strain 154 ≥ $10^{7.0}$ $TCID_{50}$*
*Tissue culture infective dose 50%

Lyophilisate: off-white or cream-coloured pellet.

4. INDICATION(S)

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.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

A diffuse swelling, up to 5 mm in diameter, may commonly be observed at the site of injection. Occasionally this swelling may be hard and painful and last for up to 3 days post injection.

A transient acute hypersensitivity reaction – with signs that may include lethargy, facial oedema, pruritus, vomiting or diarrhoea – may occur shortly after vaccination in very rare cases. Such reaction may evolve to a more severe condition (anaphylaxis), which may be life-threatening with additional signs like dyspnoea and collapse. If such reactions occur, appropriate treatment is recommended.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Reconstitute the vaccine with 1 ml solvent or 1 ml (1 dose) of the inactivated vaccines mentioned in section 12.

Subcutaneous use.

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

Vaccination programme:
Primary vaccination course:
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.

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

9. ADVICE ON CORRECT ADMINISTRATION

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.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store in a refrigerator (2 °C – 8 °C).
Do not freeze.
Protect from light.
Keep the vials in the outer box.

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.

Shelf life after reconstitution according to directions: 30 minutes.

Do not use this veterinary medicinal product after the expiry date which is stated on the label and outer packaging after ‘EXP’. The expiry date refers to the last day of that month.

12. SPECIAL WARNING(S)

Special warnings for each target species:
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.

Special precautions for use in animals:
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 medicinal product to animals:
In the case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

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

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 Nobivac Parvo-C 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 at the same time but not mixed with the inactivated vaccine of in 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.

Overdose (symptoms, emergency procedures, antidotes):
No effects other than those indicated in section 6. In some dogs the swelling may be more painful or may be observed for a longer period.

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 above.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

November 2022

15. OTHER INFORMATION

For animal treatment only.

Pack sizes:
Cardboard or plastic box with 10 x 1 dose or 50 x 1 dose vials.
Not all pack sizes may be marketed.

MA number: Vm 01708/4361

POM-V
To be supplied only on veterinary prescription.

Distributor in Northern Ireland
Intervet Ireland Ltd.
Magna Drive
Magna Business Park
Citywest Road
Dublin 24

Approved 18 November 2022