SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac DHPPi, Lyophilisate for Suspension for Injection for Dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 1 ml contains:

Active substances:

Live canine distemper virus (CDV), strain Onderstepoort	$\geq 10^{4.0}$ $TCID_{50}$*
Live canine adenovirus type 2 (CAV_2), strain Manhattan LPV3	$\geq 10^{4.0}$ $TCID_{50}$*
Live canine parvovirus (CPV), strain 154	$\geq 10^{7.0}$ $TCID_{50}$*
Live canine parainfluenza virus (CPi), strain Cornell	$\geq 10^{5.5}$ $TCID_{50}$*

* $TCID_{50}$ = median Tissue Culture Infective Dose

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate for suspension for injection.

Off-white or cream-coloured pellet.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs.

4.2 Indications for use, specifying the target species

For active immunisation of dogs to prevent mortality and clinical signs caused by canine distemper virus infection. To reduce clinical signs of infectious hepatitis and viral excretion due to canine adenovirus type 1 infection. To prevent mortality, clinical signs and viral excretion following canine parvovirus infection. To reduce clinical signs and viral excretion caused by canine parainfluenza virus infection and to reduce clinical signs of respiratory disease and viral excretion following adenovirus type 2 infection.

Onset of immunity

1 week for canine distemper virus, canine adenovirus and canine parvovirus vaccine components
4 weeks for canine parainfluenza virus vaccine component

Duration of immunity

At least three years for the canine distemper virus, canine adenovirus and canine parvovirus vaccine components.
The duration of immunity for the canine parainfluenza virus component has not been demonstrated, but an anamnestic response is produced in dogs given a revaccination one year after basic vaccination. Annual revaccination with the canine parainfluenza virus vaccine component is recommended.

4.3 Contraindications

Only healthy dogs should be vaccinated. 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 Special warnings for each target species

The efficacy of the CDV, CAV2, CPV and CPi components 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 CDV, CAV2, CPV and CPi 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
In the case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

4.6 Adverse reactions (frequency and seriousness)

In very rare cases, 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 very rare event of a hypersensitivity reaction occurring following vaccination, administer an antihistamine, corticosteroid or adrenaline, without delay and by the most immediate route.
The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

4.7 Use during pregnancy and lactation

Can be used in pregnant bitches which have previously been vaccinated with the CDV (strain Onderstepoort), CAV2 (strain Manhattan LPV3), CPV (strain 154) and CPi (strain Cornell) antigens included in the Nobivac vaccine series.

4.8 Interaction with other medicinal products and other forms of interaction

Safety and efficacy data (viral excretion) 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.

The product information of the relevant Nobivac vaccines should be consulted before administration of the mixed product. When mixed with Nobivac leptospirosis vaccines at annual revaccination, it has been established that there is no interference with the anamnestic response induced by the injectable canine parainfluenza virus component.

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 DHPPi 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.

When Nobivac DHPPi 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.

Safety and efficacy data are available which demonstrate that this vaccine can also be administered on the same day with Nobivac Solvent or Nobivac Rabies. These can be used to reconstitute the freeze-dried Nobivac DHPPi.

No information is available on the compatibility 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

One ml solvent or 1 ml (1 dose) of inactivated vaccine (as specified in section 4.8) must be used to reconstitute the freeze-dried Nobivac DHPPi vaccine.

The contents of one vial of reconstituted vaccine should be injected subcutaneously.

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 canine distemper, infectious canine hepatitis and 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 6 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. For an optimal response to the parainfluenza component, animals should be vaccinated twice, 2-4 weeks apart with the final vaccination at 10 weeks of age or more.

The event that the initial primary course dose of Nobivac DHPPi is delayed to 10 weeks of age or older, a single dose of Nobivac Pi at 12 weeks of age or older should suffice to establish immunity for this component.

Booster vaccination:
It is recommended that dogs be revaccinated with canine distemper virus, canine adenovirus and canine parvovirus every 3 years and against canine parainfluenzavirus every year.

It was not possible to produce clinical signs of kennel cough by parainfluenza challenge in adult dogs and duration of immunity could not therefore be demonstrated, but an anamnestic response was seen in dogs given a booster one year after primary vaccination. Revaccination against parainfluenza is recommended prior to exposure to high risk environments (such as kennelling, showing or mixing with dogs of unknown vaccination history).

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 (see section 4.6). In some dogs the swelling may be more painful or may be observed for a longer period.

4.11 Withdrawal periods

Not applicable.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: live viral vaccine for dogs.

ATC code: QI07AD04

The vaccine contains attenuated antigens to stimulate active immunity against canine distemper, canine parvovirus disease, canine infectious hepatitis caused by canine adenovirus type 1 and respiratory disease caused by canine adenovirus type 2 and canine parainfluenza virus.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sorbitol
Hydrolised Gelatine
Pancreatic digest of casein
Di-Sodium phosphate 12 H_2O
Water for injections.

6.2 Incompatibilities

Do not mix with any other veterinary medicinal products, except with Nobivac Solvent, or other Nobivac dog vaccines mentioned in section 4.8.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years
Shelf life after 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. Cardboard or plastic boxes containing 10 or 50 vials

6.6 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 01708/4359

9. DATE OF FIRST AUTHORISATION

20 October 2005

10. DATE OF REVISION OF THE TEXT

November 2020

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