Canine Leptospirosis Vaccine, Inactivated, I.P
Nobivac® L4

Suspension for injection for dogs.
Subcutaneous use.
Read the package leaflet before use.
Nobivac® L4 contains chemically inactivated whole cell antigens of the serogroups Canicola, Icterohaemorrhagiae, Australis and Grippotyphosa. It is effective against Leptospirosis in dogs.

NOT FOR HUMAN USE FOR ANIMAL TREATMENT ONLY

Warning: To be sold by retail on the prescription of a "Veterinary Doctor" only.

MSD Animal Health

396154 R5

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Nobivac® L4

Suspension for injection for dogs.

Composition:
Each dose of 1 ml contains:
Inactivated *Leptospira* strains:

L. interrogans serogroup Canicola serovar Portland-vere (strain Ca-12-000)	3550-7100 U[1]
L. interrogans serogroup Icterohaemorrhagiae serovar Copenhageni (strain Ic-02-001)	290-1000 U[1]
L. interrogans serogroup Australis serovar Bratislava (strain As-05-073)	500-1700 U[1]
L. kirschneri serogroup Grippotyphosa serovar Dadas (strain Gr-01-005)	650-1300 U[1]

1 Antigenic mass ELISA units.

Target Species
Dogs

Indication(s)
For active immunisation of dogs against:
- *L. interrogans* serogroup Canicola serovar Portland-vere to reduce infection and urinary excretion
- *L. interrogans* serogroup Icterohaemorrhagiae serovar Copenhageni to reduce infection and urinary excretion
- *L. interrogans* serogroup Australis serovar Bratislava to reduce infection
- *L. kirschneri* serogroup Grippotyphosa serovar Dadas to reduce infection and urinary excretion.

Onset of immunity: 3 weeks.
Duration of immunity: 1 year.

Contraindications
None

Adverse reactions
A mild and transient increase in body temperature (≤ 1 °C) has been observed very commonly in clinical studies for a few days after vaccination, with some pups showing less activity and/or a reduced appetite. A small transient swelling at the site of injection (≤ 4 cm), which can occasionally be firm and painful on palpation, has been observed very commonly in clinical studies. Any such swelling will either have disappeared or be clearly diminished by 14 days post-vaccination.

In very rare cases, clinical signs of immune-mediated haemolytic anaemia, immune-mediated thrombocytopenia, or immune-mediated polyarthritis have been reported. In very rare cases a transient acute hypersensitivity reaction may occur. Such reactions may evolve to a more severe condition (anaphylaxis), which may be life-threatening. 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 treated, including isolated reports).

Dose & Administration
Subcutaneous use.
Before use, ensure that the vaccine is at room temperature (15°C - 25°C).

Administered two vaccinations of 1 dose (1ml) of vaccine with an interval of 4 weeks of dogs from 6 weeks of age onwards.

Vaccination scheme:
Basic vaccination: The first vaccination can be administered from 6 to 9 (*) weeks of age and the second vaccination from 10 to 13 weeks of age.
Revaccination: Dogs should be revaccinated annually with one dose (1ml) of vaccine.

(*) In case of high level of maternally derived antibodies, first vaccination is recommended at 9 weeks of age).

For simultaneous use, 1 dose of a Nobivac vaccine containing canine distemper virus, canine adenovirus type 2, canine parvovirus, and/or canine parainfluenza virus components should be reconstituted with 1 dose (1 ml) of Nobivac L4. The mixed vaccines should be at room temperature (15°C - 25°C) before they are administered by subcutaneous injection.

Advice on correct administration
Before use, allow the vaccine is at room temperature (15°C- 25°C).

PSC120551_04_R3
100x336mm
2021 V1

Withdrawal period
Not applicable

Special storage precautions
Keep out of sight and reach of children.
Store in refrigerator (2°C - 8°C).
Do not freeze. Protect from light.

Shelf life
Shelf life of the veterinary medicinal product as packaged for sale : 21 months
Shelf life after first opening the immediate packing : 10 hours
Shelf life after reconstitution of Nobivac vaccines according to directors: 45 mins.

Special warning(s)
Vaccinate only healthy animals.

Special precautions for use
Special precautions for use in animals
Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Avoid accidental self-injection or contact with the eyes. In case of ocular irritation seek medical advice immediately and show the package leaflet or the label to the physician.

Use during pregnancy
Can be used during pregnancy.

Contraindications
None.

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 vaccines of the Nobivac series containing canine distemper virus, canine adenovirus type 2, canine parvovirus and/or canine parainfluenza virus components for subcutaneous administration. The product information of the relevant Nobivac vaccines should be consulted before administration of the mixed product. When mixed with these Nobivac vaccines, the demonstrated safety and efficacy claims for Nobivac L4 are no different from those described for Nobivac L4 alone.
When mixed with Nobivac vaccines containing canine parainfluenza virus at annual revaccination, it has been established that there is no interference with the anamnestic response induced by the injectable canine parainfluenza virus component.

Safety and efficacy data are available which demonstrate that this vaccine can be administered on the same day but not mixed with vaccines of the Nobivac series containing Bordetella bronchiseptica and/or parainfluenza virus components for intranasal 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
No adverse reactions other than those mentioned under Adverse reactions were observed after the administration of a double dose of vaccine. However, these reactions may be more severe and/or last longer. For example, local swelling, which can be up to 5 cm in diameter and which may take over 5 weeks to completely disappear, may be observed at the site of injection.

Presentation
Pack sizes:
Plastic Box with 5, 10, 25 or 50 vials of 1 ml (1 dose).

Manufactured by:
Intervet International B.V.
Wim de Korverstraat 35
5831 AN Boxmeer,
The Netherland

Imported & Marketed by:
Intervet India Pvt Ltd. Sagar Complex Bldg. B-1,
Gala No. 12 to 16, Ovali Village, Bhiwandi,
Thane- 421302
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