PARTICULARS TO APPEAR ON THE OUTER PACKAGE

PLASTIC BOX with 5, 10, 25 or 50 vials of 1 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac L4 suspension for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

- Four inactivated *Leptospira* strains.

3. PACKAGE SIZE

5 x 1 ml (1 dose)
10 x 1 ml (1 dose)
25 x 1 ml (1 dose)
50 x 1 ml (1 dose)

4. TARGET SPECIES

Dogs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Subcutaneous use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use immediately.

9. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator.
Do not freeze.
Protect from light.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Ltd.

14. MARKETING AUTHORISATION NUMBERS

Vm 01708/5048

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

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

Disposal: Read package leaflet.

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-V Veterinary medicinal product subject to prescription.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

GLASS VIAL LABEL of 1 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac L4

2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

1 ml (1 dose)

Four inactivated *Leptospira* strains

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use immediately.

5. ROUTE(S) OF ADMINISTRATION

SC

6. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac L4 suspension for injection for dogs

2. COMPOSITION

Each dose of 1 ml contains:

Active substances:
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.

Colourless suspension.

3. TARGET SPECIES

Dogs.

4. INDICATIONS FOR USE

For active immunisation of dogs against:
- *L. interrogans* serogroup Canicola serovar Canicola 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 Bananal/Liangguang to reduce infection and urinary excretion.

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

5. CONTRAINDICATIONS

None.

6. SPECIAL WARNINGS

Special warnings:
Vaccinate healthy animals only.

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.

Pregnancy:
Can be used during pregnancy.

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 in the Nobivac range containing canine distemper virus, canine adenovirus type 2, canine parvovirus (strain 154), 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 in the Nobivac range containing *Bordetella bronchiseptica* and/or parainfluenza virus components for intranasal administration.

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

When this vaccine is administered in association with the inactivated vaccine in the Nobivac range against *Bordetella bronchiseptica* the demonstrated antibody response data and other immunity data of this vaccine are the same as when this vaccine is administered alone.

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 in section ”Adverse Events” were observed after the administration of a double dose of vaccine. However, these reactions may be more severe and/or last longer. For example, injection site 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.

Major incompatibilities:
Do not mix with any other veterinary medicinal products except the above mentioned vaccines.

7. ADVERSE EVENTS

Dogs:

Very common (>1 animal / 10 animals treated):	Injection site swelling[1], Injection site nodule[1], Injection site pain[2], Elevated temperature[3], Decreased activity[4], Decreased appetite[4].
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersensitivity reaction[5], Immune mediated haemolytic anaemia, Immune mediated thrombocytopenia, Immune mediated polyarthritis.

[1] ≤ 4 cm; subsides within 14 days.
[2] Subsides within 14 days.
[3] ≤ 1 °C, up to 3 days.
[4] In pups.
[5] Reactions are transient. This includes anaphylaxis (sometimes fatal). If such reaction occurs appropriate treatment should be administered without delay.

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system:
Email: adverse.events@vmd.gov.uk
Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

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

Subcutaneous use.

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

Vaccination schedule:
Primary 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 re-vaccinated annually with one dose (1 ml) 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 (strain 154) and/or canine parainfluenza virus components should be reconstituted with 1 dose (1 ml) of this vaccine. The mixed vaccines should be at room temperature (15 °C – 25 °C) before they are administered by subcutaneous injection.

9. ADVICE ON CORRECT ADMINISTRATION

- Before use, ensure that the vaccine is at room temperature (15 °C – 25 °C).

10. WITHDRAWAL PERIODS

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.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after “Exp.”. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: use immediately.
Shelf life after reconstitution of Nobivac vaccines according to directions: 45 mins.

12. SPECIAL PRECAUTIONS FOR DISPOSAL

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.
Medicines should not be disposed of via wastewater.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 01708/5048

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

Not all pack sizes may be marketed.

15. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED

11/2023

Find more product information by searching for the 'Product Information Database' or 'PID' on www.gov.uk.

16. CONTACT DETAILS

Marketing authorisation holder and contact details to report suspected adverse reactions:
MSD Animal Health UK Ltd.
Walton Manor, Walton
Milton Keynes
Buckinghamshire
MK7 7AJ
Tel.: +44 (0)1908 685685

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

17. OTHER INFORMATION

For animal treatment only.

POM-V Veterinary medicinal product subject to prescription

In vitro and *in vivo* data in non-target species suggests that the vaccine may provide a degree of cross-protection against *L. interrogans* serogroup Icterohaemorrhagiae serovar Icterohaemorrhagiae and *L. kirschneri* serogroup Grippotyphosa serovar Grippotyphosa.

Approved 15 December 2023