SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac L4 suspension for injection for dogs

2. QUALITATIVE AND QUANTITATIVE 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.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection.
Colourless suspension.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs.

4.2 Indications for use, specifying the target species

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.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Vaccinate healthy animals only.

4.5 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.

Special precautions for the protection of the environment
Not applicable.

Other precautions
Not applicable.

4.6 Adverse reactions (frequency and seriousness)

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 veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See also section 16 of the package leaflet for contact details.

4.7 Use during pregnancy, lactation or lay

Can be used during pregnancy.

4.8 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.

4.9 Amount(s) to be administered and administration route

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

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.

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

No adverse reactions other than those mentioned in section 4.6 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.

4.11 Withdrawal period(s)

Not applicable.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for Canidae, inactivated bacterial vaccines.
ATCvet code: QI07AB01.

To stimulate active immunity in dogs against *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/Lianguang.

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

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium chloride
Potassium chloride
Potassium dihydrogen phosphate
Disodium phosphate dihydrate
Water for injections

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal products except those mentioned in section 4.8 above.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 21 months.
Shelf life after first opening the immediate packaging: use immediately.
Shelf life after reconstitution of Nobivac vaccines according to directions: 45 mins.

6.4 Special precautions for storage

Store in a refrigerator (2 °C – 8 °C).
Do not freeze.
Protect from light.

6.5 Nature and composition of immediate packaging

Type I glass vial of 1 ml (1 dose) closed with a halogenobutyl rubber stopper and sealed with a coded aluminium cap.

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

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

Vm 01708/5048

9. DATE OF FIRST AUTHORISATION

16 July 2012

10. DATE OF REVISION OF THE TEXT

December 2023

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

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

Approved 15 December 2023