1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac Lepto 2 suspension for injection for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml dose contains:

Active substances:
Inactivated *Leptospira interrogans* serogroups:
- Canicola; serovar Portland-vere, strain Ca-12-000 ≥ 990 Units/ml*
- Icterohaemorrhagiae; serovar Copenhageni, strain 820K ≥ 699 Units/ml*

* Antigen mass ELISA Units

Excipients:

Qualitative composition of excipients and other constituents
Sodium chloride
Potassium chloride
Potassium dihydrogen phosphate
Disodium phosphate dihydrate
Water for injections

Colourless suspension.

3. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each target species

For active immunisation from 6 weeks of age to reduce infection with *Leptospira interrogans* serogroup Canicola and *Leptospira interrogans* serogroup Icterohaemorrhagiae.
The veterinary medicinal product significantly reduces the number of animals which develop a urinary tract infection which can predispose to development of a carrier condition after *L. interrogans* serogroup Canicola and *L. interrogans* serogroup Icterohaemorrhagiae serovar Copenhageni infection.

Duration of immunity: one year.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

3.5 Special precautions for use

Special precautions for safe use in the target species:
A good immune response is reliant on the reaction of an immunogenic agent and a fully competent immune system. 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.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In the case of accidental self-injection, encourage bleeding, then disinfect the site. If symptoms develop, seek medical advice and show the package leaflet or label to the physician.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Dogs:

Very common (>1 animal / 10 animals treated):	Injection site swelling[1], Injection site reaction[1].
Rare (1 to 10 animals / 10,000 animals treated):	Hypersensitivity reaction[2],
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Anaphylaxis[2;] Immune-mediated haemolytic anaemia, immune-mediated thrombocytopenia, immune-mediated polyarthritis.

[1]For up to 3 days after vaccination.
[2] If such reactions occur, administer an antihistamine, corticosteroid or adrenaline, without delay and by the most immediate route.

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 the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:
Can be used during pregnancy.

3.8 Interaction with other medicinal products and other forms of interaction

Safety and/or efficacy data are available which demonstrate that this vaccine can be mixed with live vaccines from the Nobivac range containing canine distemper virus (strain Onderstepoort), canine adenovirus type 2 (strain Manhattan LPV3), canine parvovirus (strain 154) and/or canine parainfluenza virus (strain Cornell).

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.

Antiserum and immunosuppressive drugs may reduce the response to vaccination.

3.9 Administration routes and dosage

Subcutaneous use.
Administer 1 dose (1 ml).

Allow the vaccine to reach room temperature (15 – 25 °C) before use. Sterile injection equipment should be used.

Primary vaccination
All dogs not previously vaccinated should be vaccinated twice, with an interval of 2 – 4 weeks. Puppies should be at least 6 weeks of age before they receive the first vaccination.

Revaccination
A single annual booster dose is recommended.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

None other than those mentioned in section 3.6.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI07AB01

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product, except those mentioned in section 3.8 above.

5.2 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.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

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

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

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

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet Ireland Limited

7. MARKETING AUTHORISATION NUMBER(S)

VPA 10996/169/001

8. DATE OF FIRST AUTHORISATION

03/03/2004

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

20/03/2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).