SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac Lepto suspension for injection for dogs (DK, EL, ES, NL)
Nobivac Lepto mais suspension for injection for dogs (PT)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (1 ml) contains:

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

*Antigen mass ELISA Units

Excipients:

Qualitative composition of excipients and other constituents
Sodium chloride
Potassium chloride
Sodium-L-Lactic acid
Calcium chloride
Water for injection

Colourless suspension.

3. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each target species

Active immunisation of dogs (from the age of 8 weeks) to reduce leptospirosis caused by *Leptospira interrogans* serovars Canicola and Icterohaemorrhagiae.

Onset of immunity: 4 weeks.

Duration of immunity: 1 year against serovar Canicola and 6 months against serovar Icterohaemorrhagiae.

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:
Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In case of accidental self-injection, 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.

3.6 Adverse events

Dogs:

Very common (>1 animal / 10 animals treated):	Injection site swelling[1].
Rare (1 to 10 animals / 10,000 animals treated):	Elevated temperature[2].
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Injection site reaction. Hypersensitivity reaction (e.g. lethargy, facial oedema, pruritus, vomiting, diarrhoea)[3], anaphylaxis (e.g. dyspnoea, collapse)[3,4]. Lethargy[5], anorexia[5]. Immune-mediated haemolytic anaemia, immune-mediated thrombocytopenia, immune-mediated polyarthritis.

[1] Up to 5 cm in diameter for up to 4 days. This swelling may be hard and painful, but this will diminish gradually and disappear after 2-3 weeks.
[2] Transient.
[3] May occur shortly after vaccination.
[4] May be life-threatening. If such reactions occur, appropriate treatment is recommended.
[5] Mild.

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 its local representative> or the national competent authority via the national reporting system. See the package leaflet for respective contact details.
{< > to be adjusted nationally}

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 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 strain 154 and/or canine parainfluenza virus components for subcutaneous administration.

Safety and efficacy data are available which demonstrate that this vaccine can be administered on the same day but not mixed with Nobivac Rabies (strain Pasteur RIV).

No information is available on the safety and efficacy of this vaccine when used with any other 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.

3.9 Administration routes and dosage

Subcutaneous use.
Administer 1 dose (1 ml) per animal.

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

Basic vaccination: All dogs not previously vaccinated should be vaccinated twice with an interval of 2-4 weeks. Puppies should be at least 8 weeks of age before they receive the first vaccination.

Revaccination: Every 6-12 months.
A revaccination interval of 6 months is recommended to achieve protection against clinical leptospirosis caused by serovar Icterohaemorrhagiae.

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

No other symptoms than at single dose.

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.
{to be completed nationally}

3.12 Withdrawal periods

Not applicable.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI07AB01.

To stimulate active immunity in dogs against *Leptospira interrogans* serovars Canicola and Icterohaemorrhagiae.
The active ingredients of the vaccine induce humoral antibodies against these serovars.
Vaccination with Nobivac Lepto gives a reduction in clinical symptoms (fever and mortality) and reduces the number of animals with bacteriaemia and leptospiuria after infection, compared to unvaccinated control animals.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product, except with the vaccines mentioned under 3.8 (where these products and their combined use are authorised).

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 21 months.
Shelf life after first opening the container: 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>.
{< > to be adjusted nationally}

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

{Name}
{to be completed nationally}

7. MARKETING AUTHORISATION NUMBER(S)

{to be completed nationally}

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: {DD/MM/YYYY}.
{to be completed nationally}

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

{MM/YYYY}
{to be completed nationally}

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).

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD or PLASTIC BOX with 10 x 1 ml or 50 x 1 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac Lepto suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose (1 ml) contains:
Inactivated *L. interrogans* serogroup Canicola: ≥ 990 Units/ml
Inactivated *L. interrogans* serogroup Icterohaemorrhagiae: ≥ 699 Units/ml

3. PACKAGE SIZE

10 x 1 ml
50 x 1 ml

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.
Store in the original package. 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

{Name or company name or logo name of the marketing authorisation holder}
{to be completed nationally}

14. MARKETING AUTHORISATION NUMBERS

{number}
{to be completed nationally}

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LABEL of 1 ml vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac Lepto 

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

1 ml (1 dose)
L. interrogans Canicola and Icterohaemorrhagiae: ≥ 990 and ≥ 699 Units/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use immediately.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Nobivac Lepto suspension for injection for dogs

2. Composition

Each dose (1 ml) contains:

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

*Antigen mass ELISA Units.

Colourless suspension.

3. Target species

Dogs.

4. Indications for use

Active immunisation of dogs (from the age of 8 weeks) to reduce leptospirosis caused by *Leptospira interrogans* serovars Canicola and Icterohaemorrhagiae.

Onset of immunity: 4 weeks.

Duration of immunity: 1 year against serovar Canicola and 6 months against serovar Icterohaemorrhagiae.

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:
In case of accidental self-injection, 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 of the Nobivac series containing canine distemper virus, canine adenovirus type 2, canine parvovirus strain 154 and/or canine parainfluenza virus components for subcutaneous administration.

Safety and efficacy data are available which demonstrate that this vaccine can be administered on the same day but not mixed with Nobivac Rabies (strain Pasteur RIV).

No information is available on the safety and efficacy of this vaccine when used with any other 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 other symptoms than at single dose.

Major incompatibilities:
Do not mix with any other veterinary medicinal product, except with the vaccines mentioned above (where these products and their combined use are authorised).

7. Adverse events

Dogs:

Very common (>1 animal / 10 animals treated):	Injection site swelling[1].
Rare (1 to 10 animals / 10,000 animals treated):	Elevated temperature[2].
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Injection site reaction. Hypersensitivity reaction (e.g. lethargy, facial oedema, pruritus, vomiting, diarrhoea)[3], anaphylaxis (e.g. dyspnoea, collapse)[3,4]. Lethargy[5], anorexia[5]. Immune-mediated haemolytic anaemia, immune-mediated thrombocytopenia, immune-mediated polyarthritis.

[1] Up to 5 cm in diameter for up to 4 days. This swelling may be hard and painful, but this will diminish gradually and disappear after 2-3 weeks.
[2] Transient.
[3] May occur shortly after vaccination.
[4] May be life-threatening. If such reactions occur, appropriate treatment is recommended.
[5] Mild.

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 <or the local representative of the marketing authorisation holder> using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

{< > to be adjusted nationally}

8. Dosage for each species, routes and method of administration

Subcutaneous use.
Administer 1 dose (1 ml) per animal.

Vaccination scheme
Basic vaccination: All dogs not previously vaccinated should be vaccinated twice with an interval of 2-4 weeks. Puppies should be at least 8 weeks of age before they receive the first vaccination.

Revaccination: Every 6-12 months.
A revaccination interval of 6 months is recommended to achieve protection against clinical leptospirosis caused by serovar Icterohaemorrhagiae.

9. Advice on correct administration

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

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.
Store in the original package. Protect from light.

Once broached use immediately.

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.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or <household waste>.
{< > to be adjusted nationally}

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 applicable national collection systems. These measures should help to protect the environment

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Pack sizes:

Cardboard or plastic box with 10 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

{MM/YYYY}
{to be completed nationally}

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

16. Contact details

Marketing authorisation holder <and manufacturer responsible for batch release> <and contact details to report suspected adverse reactions>:
{< > to be adjusted nationally}

<Manufacturer responsible for batch release:> {to be adjusted nationally if included in the above}
Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

<Local representative< and contact details to report suspected adverse reactions>:>
{< > to be adjusted nationally}

<For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.>
{< > to be adjusted nationally}

17. Other information

To stimulate active immunity in dogs against *Leptospira interrogans* serovars Canicola and Icterohaemorrhagiae. The active ingredients of the vaccine induce humoral antibodies against these serovars.
Vaccination with Nobivac Lepto gives a reduction in clinical symptoms (fever and mortality) and reduces the number of animals with bacteriaemia and leptospiuria after infection, compared to unvaccinated control animals.

{to be completed nationally}