ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Canigen 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.

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 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.

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:
Avoid accidental self-injection or contact with the eyes. In case of eye contact, rinse the eye(s) with water. In case of self-injection or 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.

3.6 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 veterinary medicinal product. Reports should be sent, preferably via a veterinarian, using the contact details at the end of the package leaflet, or to the national competent authority via the national reporting system in section 'Adverse events' of the package leaflet.

3.7 Use during pregnancy, lactation or lay

Can be used during pregnancy.

3.8 Interaction with other medicinal products and other forms of interaction

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

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

No adverse reactions other than those mentioned in section 3.6 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.

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

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/Liangguang.

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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal products.

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.
Protect from light.

5.4 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 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 product 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 International B.V.

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/15/183/001-002

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 03/07/2015.

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

{MM/YYYY}

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).

ANNEX II

OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

None

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

PLASTIC BOX with 10 or 50 vials of 1 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Canigen L4 suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Inactivated *Leptospira* strains

3. PACKAGE SIZE

10 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

Intervet International B.V.

14. MARKETING AUTHORISATION NUMBER(S)

EU/2/15/183/001 (10 x 1 ml)
EU/2/15/183/002 (50 x 1 ml)

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

GLASS VIAL LABEL of 1 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Canigen L4

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

1 ml (1 dose)
Inactivated *Leptospira* strains

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

Canigen 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 eye contact, rinse the eye(s) with water. In case of self-injection or 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:
No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product. 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.

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 using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

8. Dosage for each species, routes 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.

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.

12. Special precautions for disposal

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 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

EU/2/15/183/001-002

Pack sizes:
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}

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:
Intervet International B.V.,Wim de Körverstraat 35, 5831 AN Boxmeer, The Netherlands

and contact details to report suspected adverse reactions:

België/Belgique/Belgien:
VIRBAC,
1ère avenue 2065 m – L.I.D.,
FR-06516 Carros,
France/ Frankrijk/Frankreich
Tel: + 33 (0) 4 92 08 73 00

Република България:
VIRBAC,
1ère avenue 2065 m – L.I.D.,
FR-06516 Carros,
Франция
Tel: + 33 (0) 4 92 08 73 00

Česká republika:
VIRBAC,
1ère avenue 2065 m – L.I.D.,
FR-06516 Carros,
Francie,
Tel: + 33 (0) 4 92 08 73 00

Danmark:
VIRBAC,
1ère avenue 2065 m – L.I.D.,
FR-06516 Carros,
Frankrig,
Tel: + 33 (0) 4 92 08 73 00

Deutschland:
VIRBAC,
1ère avenue 2065 m – L.I.D.,
FR-06516 Carros,
Frankreich,
Tel: + 33 (0) 4 92 08 73 00

Eesti:
VIRBAC,
1ère avenue 2065 m – L.I.D.,
FR-06516 Carros,
Prantsusmaa,
Tel: + 33 (0) 4 92 08 73 00

Lietuva:
VIRBAC,
1ère avenue 2065 m – L.I.D.,
FR-06516 Carros,
Prancūzija,
Tel: + 33 (0) 4 92 08 73 00

Luxembourg/Luxemburg:
VIRBAC,
1ère avenue 2065 m – L.I.D.,
FR-06516 Carros,
France,
Tel: + 33 (0) 4 92 08 73 00

Magyarország:
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FR-06516 Carros,
Franciaország,
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FR-06516 Carros,
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Nederland:
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Tél : +33 805 05 55 55

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Ireland:
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FR-06516 Carros,
France,
Tel: + 33 (0) 4 92 08 73 00

Ísland:
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Sími: + 33 (0) 4 92 08 73 00

Italia:
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Κύπρος:
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Portugal:
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FR-06516 Carros,
França,
Tel: + 33 (0) 4 92 08 73 00

România:
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Franţa,
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Slovenija:
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Slovenská republika:
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Suomi/Finland:
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FR-06516 Carros,
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Puh/Tel: + 33 (0) 4 92 08 73 00

Sverige:
VIRBAC,
1ère avenue 2065 m – L.I.D.,
FR-06516 Carros,
Frankrike,
Tel: + 33 (0) 4 92 08 73 00

Latvija:
VIRBAC,
1ère avenue 2065 m – L.I.D.,
FR-06516 Carros,
Francija,
Tel: + 33 (0) 4 92 08 73 00

United Kingdom (Northern Ireland):
VIRBAC,
1ère avenue 2065 m – L.I.D.,
FR-06516 Carros,
France,
Tel: + 33 (0) 4 92 08 73 00

17. Other information

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.