ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Versican Plus L4 suspension for injection for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 1 ml contains:

Active substances:

Suspension (inactivated):

Leptospira interrogans serogroup Icterohaemorrhagiae serovar Icterohaemorrhagiae strain MSLB 1089	ALR* titre ≥ 1:51
Leptospira interrogans serogroup Canicola serovar Canicola, strain MSLB 1090	ALR* titre ≥ 1:51
Leptospira kirschneri serogroup Grippotyphosa serovar Grippotyphosa, strain MSLB 1091	ALR* titre ≥ 1:40
Leptospira interrogans serogroup Australis serovar Bratislava, strain MSLB 1088	ALR* titre ≥ 1:51

* Antibody micro agglutination-lytic reaction.

Adjuvant:

Aluminium hydroxide	1.8–2.2 mg.

Excipients:

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

The visual appearance is as follows: whitish liquid with fine sediment.

3. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each target species

Active immunisation of dogs from 6 weeks of age:

- to prevent clinical signs, infection and urinary excretion caused by *L. interrogans* serogroup Australis serovar Bratislava,
- to prevent clinical signs and urinary excretion and reduce infection caused by *L. interrogans* serogroup Canicola serovar Canicola and *L. interrogans* serogroup Icterohaemorrhagiae serovar Icterohaemorrhagiae and
- to prevent clinical signs and reduce infection and urinary excretion caused by *L. kirschneri* serogroup Grippotyphosa serovar Grippotyphosa.

Onset of immunity:
4 weeks after completion of the primary course.

Duration of immunity:
At least one year following the primary vaccination course for all components of Versican Plus L4.

3.3 Contraindications

None.

3.4 Special warnings

A good immune response is reliant on a fully competent immune system. Immunocompetence of the animal may be compromised by a variety of factors including poor health, nutritional status, genetic factors, concurrent medicinal therapy and stress.

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:

Common (1 to 10 animals / 100 animals treated):	injection site swelling[1]
Rare (1 to 10 animals / 10,000 animals treated):	hypersensitivity reaction[2] (anaphylaxis, angioedema, circulatory shock, collapse, diarrhoea, dyspnoea, vomiting) anorexia, decreased activity
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	hyperthermia, lethargy, malaise immune mediated haemolytic anaemia, immune mediated haemolytic thrombocytopenia, immune mediated polyarthritis

[1]A transient swelling (up to 5 cm) which can be painful, warm or reddened. Any such swelling will either have spontaneously resolved or be greatly diminished by 14 days after vaccination.

[2]If a hypersensitivity reaction occurs, appropriate treatment should be administered without delay. Such reactions may evolve to a more severe condition which may be life-threatening.

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 and lactation:

Can be used during the second and third stages of pregnancy. Safety of the product during the early stage of pregnancy and during lactation has not been investigated.

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 other than Versican Plus DHPPi and Versican Plus Pi. 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.

Vaccination against distemper, adeno, parvo and parainfluenza virus (DHPPi):
If protection against DHPPi or Pi is required, dogs can be vaccinated with two doses of Versican Plus DHPPi or Versican Plus Pi mixed with Versican Plus L4 3–4 weeks apart from 6 weeks of age:
The contents of a single vial of Versican Plus DHPPi or Versican Plus Pi should be reconstituted with the contents of a single vial of Versican Plus L4 (instead of the solvent). Once mixed, the contents of the vial should appear a whitish to yellowish colour with light opalescence (Pi/L4) or pinkish or yellowish colour with light opalescence (DHPPi/L4). The mixed vaccines should be injected immediately via the subcutaneous route.

3.9 Administration routes and dosage

Subcutaneous use.

Dosage and route of administration:
Shake well and administer immediately the entire contents (1 ml) of the product.

Primary vaccination scheme:
Two doses of Versican Plus L4 3-4 weeks apart from 6 weeks of age.

Re-vaccination scheme:
A single dose of Versican Plus L4 to be given annually.

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

No data are available on the safety of an overdose.

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

The vaccine is intended for the active immunisation of healthy puppies and dogs against diseases caused by *Leptospira interrogans* serogroup Australis serovar Bratislava, *Leptospira interrogans* serogroup Canicola serovar Canicola, *Leptospira kirschneri* serogroup Grippotyphosa serovar Grippotyphosa and *Leptospira interrogans* serogroup Icterohaemorrhagiae serovar Icterohaemorrhagiae.

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: 2 years.
Shelf life after first opening the immediate packaging: use immediately.

5.3 Special precautions for storage

Store and transport refrigerated (2 °C – 8 °C).
Do not freeze.
Protect from light.

5.4 Nature and composition of immediate packaging

Type I glass vial containing 1 ml closed with a chlorobutyl rubber stopper and aluminium cap.

Pack sizes:
Plastic box containing 25 vials (1 ml).
Plastic box containing 50 vials (1 ml).

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

Zoetis Belgium

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/14/171/001
EU/2/14/171/002

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 31/07/2014.

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

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

BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Versican Plus L4 suspension for injection.

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose of 1 ml contains:

Active substances:

Suspension (inactivated):

L. interrogans serovar Icterohaemorrhagiae	ALR titre ≥ 1:51
L. interrogans serovar Canicola	ALR titre ≥ 1:51
L. kirschneri serovar Grippotyphosa	ALR titre ≥ 1:40
L. interrogans serovar Bratislava	ALR titre ≥ 1:51

3. PACKAGE SIZE

25 x 1 dose
50 x 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 and transport refrigerated.
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

Zoetis Belgium

14. MARKETING AUTHORISATION NUMBERS

EU/2/14/171/001 25 x 1 dose
EU/2/14/171/002 50 x 1 dose

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

VIAL (1 ML SUSPENSION)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Versican Plus L4

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

L4
1 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

Versican Plus L4 suspension for injection for dogs

2. Composition

Each dose of 1 ml contains:

Active substances:

Suspension (inactivated):

Leptospira interrogans serogroup Icterohaemorrhagiae serovar Icterohaemorrhagiae strain MSLB 1089	ALR* titre ≥ 1:51
Leptospira interrogans serogroup Canicola serovar Canicola, strain MSLB 1090	ALR* titre ≥ 1:51
Leptospira kirschneri serogroup Grippotyphosa serovar Grippotyphosa, strain MSLB 1091	ALR* titre ≥ 1:40
Leptospira interrogans serogroup Australis serovar Bratislava, strain MSLB 1088	ALR* titre ≥ 1:51

* Antibody micro agglutination-lytic reaction.

Adjuvant:

Aluminium hydroxide	1.8–2.2 mg.

The visual appearance is as follows: whitish liquid with fine sediment.

3. Target species

Dogs.

4. Indications for use

Active immunisation of dogs from 6 weeks of age:

- to prevent clinical signs, infection and urinary excretion caused by *L. interrogans* serogroup Australis serovar Bratislava,
- to prevent clinical signs and urinary excretion and reduce infection caused by *L. interrogans* serogroup Canicola serovar Canicola and *L. interrogans* serogroup Icterohaemorrhagiae serovar Icterohaemorrhagiae and
- to prevent clinical signs and reduce infection and urinary excretion caused by *L. kirschneri* serogroup Grippotyphosa serovar Grippotyphosa.

Onset of immunity:
4 weeks after the completion of primary course.

Duration of immunity:
At least one year following the primary vaccination course for all components of Versican Plus L4.

5. Contraindications

None.

6. Special warnings

Special warnings:
A good immune response is reliant on a fully competent immune system. Immunocompetence of the animal may be compromised by a variety of factors including poor health, nutritional status, genetic factors, concurrent medicinal therapy and stress.

Vaccinate healthy animals only.

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.

Pregnancy and lactation:
Can be used during the second and third stages of pregnancy. Safety of the product during the early stage of pregnancy and during lactation has not been investigated.

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 other than Versican Plus DHPPi and Versican Plus Pi. 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.

Vaccination against distemper, adeno, parvo and parainfluenza virus (DHPPi):
If protection against *DHPPi* or *Pi* is required, dogs can be vaccinated with two doses of Versican Plus DHPPi or Versican Plus Pi mixed with Versican Plus L4 3–4 weeks apart from 6 weeks of age:
The contents of a single vial of Versican Plus DHPPi or Versican Plus Pi should be reconstituted with the contents of a single vial of Versican Plus L4 (instead of the solvent). Once mixed, the contents of the vial should appear a whitish to yellowish colour with light opalescence (Pi/L4) or pinkish or yellowish colour with light opalescence (DHPPi/L4). The mixed vaccines should be injected immediately via the subcutaneous route.

Overdose:
No data are available on the safety of an overdose.

Special restrictions for use and special conditions for use:
Not applicable.

Major incompatibilities:
Do not mix with any other veterinary medicinal product except those mentioned in section “Interaction with other medicinal products and other forms of interaction”.

7. Adverse events

Dogs:

Common (1 to 10 animals / 100 animals treated):
injection site swelling[1]
Rare (1 to 10 animals / 10,000 animals treated):
hypersensitivity reaction[2] (anaphylaxis, angioedema, circulatory shock, collapse, diarrhoea, dyspnoea, vomiting) anorexia, decreased activity
Very rare (<1 animal / 10,000 animals treated, including isolated reports):
hyperthermia, lethargy, malaise immune mediated haemolytic anaemia, immune mediated haemolytic thrombocytopenia, immune mediated polyarthritis

[1]A transient swelling (up to 5 cm) which can be painful, warm or reddened. Any such swelling will either have spontaneously resolved or be greatly diminished by 14 days after vaccination.

[2]If a hypersensitivity reaction occurs, appropriate treatment should be administered without delay. Such reactions may evolve to a more severe condition which may be life-threatening.

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: {national system details}.

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

Subcutaneous use.

Primary vaccination scheme:
Two doses of Versican Plus L4 3–4 weeks apart from 6 weeks of age.

Re-vaccination scheme:
A single dose of Versican Plus L4 to be given annually.

9. Advice on correct administration

Shake well and administer immediately the entire contents (1 ml) of the product.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

Store and transport refrigerated (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/2/14/171/001-002

Plastic box containing 25 vials (1 ml).
Plastic box containing 50 vials (1 ml).

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 contact details to report suspected adverse reactions:
Zoetis Belgium
Rue Laid Burniat 1
1348 Louvain-La-Neuve
Belgium

België/Belgique/Belgien
Tél/Tel: +32 (0) 800 99 189
pharmvig-belux@zoetis.com

Република България
Тел: +359 888 51 30 30
zoetisromania@zoetis.com

Lietuva
Tel: +370 610 05088
zoetis.lithuania@zoetis.com

Luxembourg/Luxemburg
Tél/Tel: +32 (2) 746 80 11
pharmvig-belux@zoetis.com

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laaketurva@zoetis.com

Sverige
Tel: +46 (0) 76 760 0677
adr.scandinavia@zoetis.com

United Kingdom (Northern Ireland)
Tel: +353 (0) 1 256 9800
pvsupportireland@zoetis.com

Manufacturer responsible for batch release:
Bioveta a.s.
Komenskeho 212/12
683 23 Ivanovice Na Hane
Czechia

17. Other information

The vaccine is intended for the active immunisation of healthy puppies and dogs against diseases caused by *Leptospira interrogans* serogroup Australis serovar Bratislava, *Leptospira interrogans* serogroup Canicola serovar Canicola, *Leptospira kirschneri* serogroup Grippotyphosa serovar Grippotyphosa and *Leptospira interrogans* serogroup Icterohaemorrhagiae serovar Icterohaemorrhagiae.