

**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):**

<i>Leptospira interrogans</i> serogroup Icterohaemorrhagiae serovar Icterohaemorrhagiae strain MSLB 1089	ALR* titre $\geq$ 1:51
<i>Leptospira interrogans</i> serogroup Canicola serovar Canicola, strain MSLB 1090	ALR* titre $\geq$ 1:51
<i>Leptospira kirschneri</i> serogroup Grippotyphosa serovar Grippotyphosa, strain MSLB 1091	ALR* titre $\geq$ 1:40
<i>Leptospira interrogans</i> serogroup Australis serovar Bratislava, strain MSLB 1088	ALR* titre $\geq$ 1:51

\* Antibody micro agglutination-lytic reaction.

### Adjuvant:

Aluminium hydroxide 1.8–2.2 mg.

### Excipients:

Qualitative composition of excipients and other constituents
<b>Suspension:</b>
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 <sup>1</sup>
Rare (1 to 10 animals / 10,000 animals treated):	hypersensitivity reaction <sup>2</sup> (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

<sup>1</sup>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.

<sup>2</sup>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 its local representative or the national competent authority via the national reporting system. See section “Contact details” of the package leaflet.

### **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):**

<i>L. interrogans</i> serovar Icterohaemorrhagiae	ALR titre $\geq$ 1:51
<i>L. interrogans</i> serovar Canicola	ALR titre $\geq$ 1:51
<i>L. kirschneri</i> serovar Grippotyphosa	ALR titre $\geq$ 1:40
<i>L. interrogans</i> serovar Bratislava	ALR titre $\geq$ 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):

<i>Leptospira interrogans</i> serogroup Icterohaemorrhagiae serovar Icterohaemorrhagiae strain MSLB 1089	ALR* titre $\geq$ 1:51
<i>Leptospira interrogans</i> serogroup Canicola serovar Canicola, strain MSLB 1090	ALR* titre $\geq$ 1:51
<i>Leptospira kirschneri</i> serogroup Grippotyphosa serovar Grippotyphosa, strain MSLB 1091	ALR* titre $\geq$ 1:40
<i>Leptospira interrogans</i> serogroup Australis serovar Bratislava, strain MSLB 1088	ALR* titre $\geq$ 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 <sup>1</sup>
Rare (1 to 10 animals / 10,000 animals treated):
hypersensitivity reaction <sup>2</sup> (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

<sup>1</sup>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.

<sup>2</sup>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 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}.

## 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**

{DD/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:

Zoetis Belgium  
Rue Laid Burniat 1  
1348 Louvain-La-Neuve  
Belgium

### Manufacturer responsible for batch release:

Bioveta a.s.  
Komenskeho 212/12  
683 23 Ivanovice Na Hane  
Czechia

### Local representatives and contact details to report suspected adverse reactions:

**België/Belgique/Belgien**

Zoetis Belgium  
Mercuriusstraat 20  
BE-1930 Zaventem  
Tél/Tel: +32 (0) 800 99 189

**Република България**

Zoetis Belgium  
Rue Laid Burniat 1  
1348 Louvain-la-Neuve  
Белгия  
Тел: +359 888 51 30 30

**Česká republika**

Zoetis Česká republika, s.r.o.  
náměstí 14. října 642/17  
CZ 150 00 Praha  
Tel: +420 257 101 111

**Danmark**

Zoetis Animal Health ApS  
Øster Alle 48  
DK-2100 København  
Tlf: +45 70 20 73 05  
[adr.scandinavia@zoetis.com](mailto:adr.scandinavia@zoetis.com)

**Deutschland**

Zoetis Deutschland GmbH  
Schellingstr. 1  
DE-10785 Berlin  
Tel: +49 30 2020 0049  
[tierarzneimittelsicherheit@zoetis.com](mailto:tierarzneimittelsicherheit@zoetis.com)

**Eesti**

Zoetis Belgium  
Mercuriusstraat 20  
1930 Zaventem  
Belgia  
Tel: +370 610 05088

**Κύπρος**

Zoetis Hellas S.A.  
Φραγκοκκλησιάς 7, Μαρούσι  
15125, Αττική  
Ελλάδα  
Τηλ: +30 210 6791900

**España**

Zoetis Spain, S.L.  
Parque Empresarial Vía Norte Edificio nº1,  
c/ Quintanavides nº13  
ES-28050 Madrid  
Tel: +34 91 4191900

**Lietuva**

Zoetis Belgium  
Mercuriusstraat 20  
1930 Zaventem  
Belgija  
Tel: +370 610 05088

**Luxembourg/Luxemburg**

Zoetis Belgium  
Mercuriusstraat 20  
1930 Zaventem  
Belsch  
Tél/Tel: +32 (2) 746 80 11

**Magyarország**

Zoetis Hungary Kft.  
Csörsz u. 41.  
HU-1124 Budapest  
Tel.: +36 1 224 5200

**Malta**

Agrimed Limited  
Mdina Road, Zebbug ZBG 9016,  
MT  
Tel: +356 21 465 797

**Nederland**

Zoetis B.V.  
Rivium Westlaan 74  
NL-2909 LD Capelle aan den IJssel  
Tel: +31 (0)10 714 0900

**Norge**

Zoetis Animal Health ApS  
Øster Alle 48  
DK-2100 København  
Danmark  
Tlf: +47 23 29 86 80  
[adr.scandinavia@zoetis.com](mailto:adr.scandinavia@zoetis.com)

**Österreich**

Zoetis Österreich GmbH  
Floridsdorfer Hauptstr. 1  
AT-1210 Wien  
Tel: +43 (0)1 2701100 100

**Polska**

Zoetis Polska Sp. z o.o.  
ul. Postępu 17B  
PL - 02-676 Warszawa  
Tel.: +48 22 2234800

**France**

Zoetis France  
10 rue Raymond David  
FR-92240 Malakoff  
Tél: +33 (0)800 73 00 65

**Hrvatska**

Zoetis B.V.  
Podružnica Zagreb za promidžbu  
Petra Hektorovića 2  
HR-10000 Zagreb  
Tel: +385 1 6441 462

**Ireland**

Zoetis Belgium S.A. (Irish Branch)  
2nd Floor, Building 10,  
Cherrywood Business Park,  
Loughlinstown,  
Co. Dublin,  
IE – Dublin D18 T3Y1  
Tel: +353 (0) 1 256 9800

**Ísland**

Zoetis Animal Health ApS  
Øster Alle 48  
DK-2100 København  
Danmörku  
Sími: +45 70 20 73 05  
[adr.scandinavia@zoetis.com](mailto:adr.scandinavia@zoetis.com)

**Italia**

Zoetis Italia S.r.l.  
Via Andrea Doria 41M,  
IT-00192 Roma  
Tel: +39 06 3366 8111

**Ελλάδα**

Zoetis Hellas S.A.  
Φραγκοκκλησιάς 7, Μαρούσι  
EL-15125 Αττική  
Τηλ: +30 210 6791900

**Latvija**

Zoetis Belgium  
Mercuriusstraat 20  
1930 Zaventem  
Belgija  
Tel: +370 610 05088

**Portugal**

Zoetis Portugal Lda.  
Lagoas Park, Edificio 10  
PT-2740-271 Porto Salvo  
Tel: +351 21 042 72 00

**România**

Zoetis România S.R.L.  
Expo Business Park, 54A Aviator Popișteanu,  
Clădirea 2, Etaj 1-3, Sector 1,  
București, 012095 - RO  
Tel: +40785019479

**Slovenija**

Zoetis B.V.  
Podružnica Zagreb za promidžbu  
Petra Hektorovića 2,  
10000 Zagreb,  
Hrvaška  
Tel: +385 1 6441 462

**Slovenská republika**

Zoetis Česká republika, s.r.o.  
náměstí 14. října 642/17  
150 00 Praha  
Česká republika  
Tel: +420 257 101 111

**Suomi/Finland**

Zoetis Finland Oy  
Bulevardi 21 / SPACES  
FI-00180 Helsinki/Helsingfors  
Suomi/Finland  
Puh/Tel: +358 10 336 7000  
[laaketurva@zoetis.com](mailto:laaketurva@zoetis.com)

**Sverige**

Zoetis Animal Health ApS  
Øster Alle 48  
DK-2100 Köpenhamn  
Danmark  
Tel: +46 (0) 76 760 0677  
[adr.scandinavia@zoetis.com](mailto:adr.scandinavia@zoetis.com)

**United Kingdom (Northern Ireland)**

Zoetis Belgium S.A. (Irish Branch)  
2nd Floor, Building 10,  
Cherrywood Business Park,  
Loughlinstown,  
Co. Dublin,  
IE – Dublin D18 T3Y1  
Tel: +353 (0) 1 256 9800

## **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.