

ANNEX I
SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Versican Plus Pi/L4 lyophilisate and suspension for suspension for injection for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml dose contains:

Active substances:

Lyophilisate (live attenuated):

Canine parainfluenza Type 2 virus, strain CPiV-2 Bio 15

Minimum

$10^{3.1}$ TCID₅₀*

Maximum

$10^{5.1}$ TCID₅₀*

Suspension (inactivated):

Leptospira interrogans serogroup Icterohaemorrhagiae

serovar Icterohaemorrhagiae strain MSLB 1089

ALR** titre \geq 1:51

Leptospira interrogans serogroup Canicola

serovar Canicola, strain MSLB 1090

ALR** titre \geq 1:51

Leptospira kirschneri serogroup Grippotyphosa

serovar Grippotyphosa, strain MSLB 1091

ALR** titre \geq 1:40

Leptospira interrogans serogroup Australis

serovar Bratislava, strain MSLB 1088

ALR** titre \geq 1:51

*Tissue culture infectious dose 50%.

**Antibody micro agglutination-lytic reaction.

Adjuvants:

Aluminium hydroxide

1.8–2.2 mg.

Excipients:

Qualitative composition of excipients and other constituents
Lyophilisate:
Trometamol
Edetic Acid
Sucrose
Dextran 70
Suspension:
Sodium chloride
Potassium chloride
Potassium dihydrogen phosphate
Disodium phosphate dodecahydrate
Water for injections

The visual appearance is as follows:

Lyophilisate: spongy matter of white colour.

Suspension: whitish colour 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 (nasal and ocular discharge) and reduce viral excretion caused by canine parainfluenza virus,
- 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:

- 3 weeks after completion of the primary course for CPiV and
- 4 weeks after completion of the primary course for *Leptospira* components.

Duration of immunity:

At least one year following the primary vaccination course for all components of Versican Plus Pi/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:

The live attenuated virus vaccine strain CPiV may be shed by vaccinated dogs following vaccination. However, due to the low pathogenicity of the strain, it is not necessary to keep vaccinated dogs separated from non-vaccinated dogs.

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):	Injection site lump, Injection site mass, Injection site nodule Hyperthermia, Lethargy, Malaise Immune mediated haemolytic anaemia, Immune mediated haemolytic thrombocytopenia, Immune mediated polyarthritis

¹A 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.

²If 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. 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.

Dosage and route of administration:

Aseptically reconstitute the lyophilisate with the suspension. Shake well and administer immediately the entire contents (1 ml) of the reconstituted product.

Appearance of the reconstituted vaccine: whitish to yellowish colour with light opalescence.

Primary vaccination scheme:

Two doses of Versican Plus Pi/L4 3–4 weeks apart from 6 weeks of age.

Re-vaccination scheme:

A single dose of Versican Plus Pi/L4 to be given annually.

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

No adverse events other than those mentioned in section 3.6 were observed after administration of a 10-fold overdose of the vaccine. However, in a minority of animals pain was observed at the injection site immediately after administration of a 10-fold overdose of the vaccine.

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 : QI07AI08

The vaccine is intended for the active immunisation of healthy puppies and dogs against diseases caused by canine parainfluenza virus, *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

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after reconstitution according to directions: 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 dose of lyophilisate closed with a bromobutyl rubber stopper and aluminium cap.
Type I glass vial containing 1 ml of suspension closed with a chlorobutyl rubber stopper and aluminium cap.

Pack sizes:

Plastic box containing 25 vials (1 dose) of lyophilisate and 25 vials (1 ml) of suspension.
Plastic box containing 50 vials (1 dose) of lyophilisate and 50 vials (1 ml) of suspension.

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/2/14/172/001

EU/2/14/172/002

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

{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**BOX****1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Versican Plus Pi/L4 Lyophilisate and suspension for suspension for injection.

2. STATEMENT OF ACTIVE SUBSTANCES

Each 1 ml dose contains:

Active substances:**Lyophilisate (live attenuated):**

Canine parainfluenza virus Type 2

Minimum
10^{3.1} TCID₅₀

Maximum
10^{5.1} TCID₅₀

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 reconstituted 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/2/14/172/001 (25 x 1 dose)
EU/2/14/172/002 (50 x 1 dose)

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS
VIAL (1 DOSE LYOPHILISATE)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Versican Plus Pi/L4



2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Pi
1 dose

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

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

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS
VIAL (1 ML SUSPENSION)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Versican Plus Pi/L4



2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

L4
1 ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Versican Plus Pi/L4 lyophilisate and suspension for suspension for injection for dogs

2. Composition

Each 1 ml dose contains:

Active substances:

Lyophilisate (live attenuated):

Canine parainfluenza Type 2 virus, strain CPiV-2 Bio 15

Minimum

$10^{3.1}$ TCID₅₀*

Maximum

$10^{5.1}$ TCID₅₀*

Suspension (inactivated):

Leptospira interrogans serogroup Icterohaemorrhagiae
serovar Icterohaemorrhagiae strain MSLB 1089

ALR** titre \geq 1:51

Leptospira interrogans serogroup Canicola
serovar Canicola, strain MSLB 1090

ALR** titre \geq 1:51

Leptospira kirschneri serogroup Grippotyphosa
serovar Grippotyphosa, strain MSLB 1091

ALR** titre \geq 1:40

Leptospira interrogans serogroup Australis
serovar Bratislava, strain MSLB 1088

ALR** titre \geq 1:51

*Tissue culture infectious dose 50%.

**Antibody micro agglutination-lytic reaction.

Adjuvants:

Aluminium hydroxide

1.8–2.2 mg.

The visual appearance is as follows:

Lyophilisate: spongy matter of white colour.

Suspension: whitish colour with fine sediment.

3. Target species

Dogs.

4. Indications for use

Active immunisation of dogs from 6 weeks of age:

- to prevent clinical signs (nasal and ocular discharge) and reduce viral excretion caused by canine parainfluenza virus,
- 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:

- 3 weeks after completion of the primary course for CPiV and
- 4 weeks after completion of the primary course for *Leptospira* components.

Duration of immunity:

At least one year following the primary vaccination course for all components of Versican Plus Pi/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:

The live attenuated virus vaccine strain CPiV may be shed by vaccinated dogs following vaccination. However, due to the low pathogenicity of the strain, it is not necessary to keep vaccinated dogs separated from non-vaccinated dogs.

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 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. 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 events other than those mentioned in section "Adverse events" were observed after administration of a 10-fold overdose of the vaccine. However, in a minority of animals pain was observed at the injection site immediately after administration of a 10-fold overdose of the vaccine.

Major incompatibilities:

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

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):
Injection site lump, Injection site mass, Injection site nodule Hyperthermia, Lethargy, Malaise Immune mediated haemolytic anaemia, Immune mediated haemolytic thrombocytopenia, Immune mediated polyarthritis

¹A 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.

²If 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 Pi/L4 3–4 weeks apart from 6 weeks of age.

Re-vaccination scheme:

A single dose of Versican Plus Pi/L4 to be given annually.

9. Advice on correct administration

Aseptically reconstitute the lyophilisate with the suspension. Shake well and administer immediately the entire contents (1 ml) of the reconstituted product.

Appearance of the reconstituted vaccine: whitish to yellowish colour with light opalescence.

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 reconstitution according to directions: 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/2/14/172/001-002

Plastic box containing 25 vials (1 dose) of lyophilisate and 25 vials (1 ml) of suspension.
Plastic box containing 50 vials (1 dose) of lyophilisate and 50 vials (1 ml) of suspension.

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 events:

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

Česká republika
Tel: +420 257 101 111
infovet.cz@zoetis.com

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

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

Magyarország
Tel.: +36 1 224 5200
hungary.info@zoetis.com

Danmark

Tlf: +45 70 20 73 05

adr.scandinavia@zoetis.com**Deutschland**

Tel: +49 30 2020 0049

tierarzneimittelsicherheit@zoetis.com**Eesti**

Tel: +370 610 05088

zoetis.estonia@zoetis.com**Ελλάδα**

Τηλ: +30 210 6791900

infoqr@zoetis.com**España**

Tel: +34 91 4191900

regulatory.spain@zoetis.com**France**

Tél: +33 (0)800 73 00 65

contacteznous@zoetis.com**Hrvatska**

Tel: +385 1 6441 462

pv.westernbalkans@zoetis.com**Ireland**

Tel: +353 (0) 1 256 9800

pvsupportireland@zoetis.com**Ísland**

Sími: +354 540 8000

icepharma@icepharma.is**Italia**

Tel: +39 06 3366 8111

farmacovigilanza.italia@zoetis.com**Κύπρος**

Τηλ: +30 210 6791900

infoqr@zoetis.com**Latvija**

Tel: +370 610 05088

zoetis.latvia@zoetis.com**Malta**

Tel: +356 21 465 797

info@agrimedltd.com**Nederland**

Tel: +31 (0)10 714 0900

pharmvig-nl@zoetis.com**Norge**

Tlf: +47 23 29 86 80

adr.scandinavia@zoetis.com**Österreich**

Tel: +43 (0)1 2701100 100

tierarzneimittelsicherheit@zoetis.com**Polska**

Tel.: +48 22 2234800

pv.poland@zoetis.com**Portugal**

Tel: +351 21 042 72 00

zoetis.portugal@zoetis.com**România**

Tel: +40785019479

zoetisromania@zoetis.com**Slovenija**

Tel: +385 1 6441 462

pv.westernbalkans@zoetis.com**Slovenská republika**

Tel: +420 257 101 111

infovet.cz@zoetis.com**Suomi/Finland**

Puh/Tel: +358 10 336 7000

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.comManufacturer 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 canine parainfluenza virus, *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.