ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Versican Plus Pi/L4R lyophilisate and suspension for suspension for injection for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 1 ml contains:

Active substances:

Lyophilisate (live attenuated):	**Minimum**	**Maximum**
Canine parainfluenza Type 2 virus, strain CPiV-2 Bio 15	$10^{3.1}$ $TCID_{50}$*	$10^{5.1}$ $TCID_{50}$*

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
Rabies virus, strain SAD Vnukovo-32	≥ 5 IU***

* Tissue culture infectious dose 50%.
** Antibody micro agglutination-lytic reaction.
*** International units.

Adjuvant:

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: pink 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 8-9 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,
- to prevent clinical signs and reduce infection and urinary excretion caused by *L. kirschneri* serogroup Grippotyphosa serovar Grippotyphosa and
- to prevent mortality, clinical signs and infection caused by rabies virus.

Onset of immunity:
- 2 weeks after a single vaccination from 12 weeks of age for rabies,
- 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 three years following the primary vaccination course for rabies. At least one year following the primary vaccination course for canine parainfluenza virus and *Leptospira* components. Duration of immunity for rabies was demonstrated after one vaccination at 12 weeks of age.

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 drug therapy and stress.

Vaccinate healthy animals only.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Do not use in animals that are showing signs of rabies or that are suspected of being infected with rabies virus.

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):	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 its local representative or the national competent authority via the national reporting system. See also the last section of 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 have 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.

Dose and route of administration:
Aseptically reconstitute the lyophilisate with the suspension. Shake well and administer immediately the entire content (1 ml) of the reconstituted product.

Appearance of the reconstituted vaccine: pink/red, or yellowish colour with light opalescence.

Primary vaccination scheme:

Two doses of Versican Plus Pi/L4R 3-4 weeks apart from 8-9 weeks of age. The second dose should not be given before 12 weeks of age.

Rabies:
The efficacy of the rabies fraction is proven after a single dose from 12 weeks of age in laboratory studies. Therefore, the first dose may be given using Versican Plus Pi/L4. In this case the second vaccination with Versican Plus Pi/L4R should not be given before 12 weeks.
However, in field studies 10% of sero-negative dogs did not show seroconversion (> 0.1 IU/ml) 3–4 weeks after single primary vaccination against rabies. Some animals may also not show titres > 0.5 IU/ml after the primary vaccination. Antibody titres drop over the course of the 3-year duration of immunity, although dogs are protected when challenged. In case of travelling to risk areas or outside the EU, veterinary surgeons may wish to give additional rabies vaccinations after 12 weeks of age to ensure that the vaccinated dogs have an antibody titre of ≥ 0.5 IU/ml, which is generally regarded as sufficiently protective and that they meet the travel test requirements (antibody titres ≥ 0.5 IU/ml).

In case of need, dogs younger than 8 weeks can be vaccinated as safety of this product has been demonstrated in 6-week old dogs.

Re-vaccination scheme:
A single dose of Versican Plus Pi/L4R should be given every 3 years. Annual re-vaccination is required for canine parainfluenza virus and *Leptospira* components. Therefore a single dose of compatible vaccine Versican Plus Pi/L4 can be used annually as required.

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

Official control authority batch release is required for this product.

3.12 Withdrawal periods

Not applicable.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI07AJ.

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, *Leptospira interrogans* serogroup Icterohaemorrhagiae serovar Icterohaemorrhagiae, and rabies virus.

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 1 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 NUMBERS

EU/2/14/173/001
EU/2/14/173/002

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

TBC

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.

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/L4R lyophilisate and suspension for suspension for injection.

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose of 1 ml contains:

Active substances:

Lyophilisate (live attenuated):	**Minimum**	**Maximum**
Canine parainfluenza virus Type 2	$10^{3.1}$ $TCID_{50}$	$10^{5.1}$ $TCID_{50}$

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
Rabies virus	≥ 5 IU

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/2/14/173/001
EU/2/14/173/002

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/L4R

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/L4R

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

L4R
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/L4R lyophilisate and suspension for suspension for injection for dogs

2. Composition

Each dose of 1 ml contains:

Active substances:

Lyophilisate (live attenuated):	**Minimum**	**Maximum**
Canine parainfluenza Type 2 virus, strain CPiV-2 Bio 15	$10^{3.1}$ $TCID_{50}$*	$10^{5.1}$ $TCID_{50}$*

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
Rabies virus, strain SAD Vnukovo-32	≥ 5 IU***

* Tissue culture infectious dose 50%.
** Antibody micro agglutination-lytic reaction.
*** International units.

Adjuvant:

Aluminium hydroxide	1.8 - 2.2 mg.

The visual appearance is as follows:
Lyophilisate: spongy matter of white colour.
Suspension: pink colour with fine sediment.

3. Target species

Dogs.

4. Indications for use

Active immunisation of dogs from 8-9 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,
- to prevent clinical signs and reduce infection and urinary excretion caused by *L. kirschneri* serogroup Grippotyphosa serovar Grippotyphosa and

– to prevent mortality, clinical signs and infection caused by rabies virus.

Onset of immunity:
- 2 weeks after a single vaccination from 12 weeks of age for rabies,
- 3 weeks after completion of the primary course for CPiV and
- 4 weeks after the completion of primary course for *Leptospira* components.

Duration of immunity:
At least three years following the primary vaccination course for rabies. At least one year following the primary vaccination course for canine parainfluenza virus and *Leptospira* components. Duration of immunity for rabies was demonstrated after one vaccination at 12 weeks of age.

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 drug therapy and stress.

Vaccinate healthy animals only.

Special precautions for safe use in the target species:
Do not use in animals that are showing signs of rabies or that are suspected of being infected with rabies virus.

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.

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 have 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 7 (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.

Special restrictions for use and special conditions for use:
Official control authority batch release is required for this product.

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

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

Subcutaneous use.

Primary vaccination scheme:
Two doses of Versican Plus Pi/L4R 3-4 weeks apart from 8-9 weeks of age. The second dose should not be given before 12 weeks of age.

Rabies:
The efficacy of the rabies fraction is proven after a single dose from 12 weeks of age in laboratory studies. Therefore, the first dose may be given using Versican Plus Pi/L4. In this case the second vaccination with Versican Plus Pi/L4R should not be given before 12 weeks.

However, in field studies 10% of sero-negative dogs did not show seroconversion (> 0.1 IU/ml) 3–4 weeks after single primary vaccination against rabies. Some animals may also not show titres > 0.5 IU/ml after the primary vaccination. Antibody titres drop over the course of the 3-year duration of immunity, although dogs are protected when challenged. In case of travelling to risk areas or outside the EU, veterinary surgeons may wish to give additional rabies vaccinations after 12 weeks of age to ensure that the vaccinated dogs have an antibody titre of ≥ 0.5 IU/ml, which is generally regarded as sufficiently protective and that they meet the travel test requirements (antibody titres ≥ 0.5 IU/ml).

In case of need, dogs younger than 8 weeks can be vaccinated as safety of this product has been demonstrated in 6-week old dogs.

Re-vaccination scheme:
A single dose of Versican Plus Pi/L4R should be given every 3 years. Annual re-vaccination is required for canine parainfluenza and *Leptospira* components. Therefore a single dose of compatible vaccine Versican Plus Pi/L4 can be used annually as required.

9. Advice on correct administration

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

Appearance of the reconstituted vaccine: pink/red, or 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/2/14/173/001-002

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

Detailed information on this veterinary medicinal product is available in the Union Product Database.

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
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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, *Leptospira interrogans* serogroup Icterohaemorrhagiae serovar Icterohaemorrhagiae and rabies virus.