

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):

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

Rabies virus, strain SAD Vnukovo-32

\geq 2.0 IU***

* Tissue culture infectious dose 50 %.

** Antibody micro agglutination-lytic reaction.

*** International units.

Adjuvant:

Aluminium hydroxide

1.8 - 2.2 mg.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate and suspension for suspension for injection.

The visual appearance is as follows:

Lyophilisate: spongy matter of white colour.

Suspension: pink colour with fine sediment.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs

4.2 Indications for use, specifying the 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.

4.3 Contraindications

None.

4.4 Special warnings for each target species

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.

4.5 Special precautions for use

Special precautions for use in animals

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 animals 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.

4.6 Adverse reactions (frequency and seriousness)

A transient swelling (up to 5 cm) may commonly be observed at the injection site following subcutaneous administration in dogs. This can be painful, warm or reddened. Any such swelling will either have spontaneously resolved or be greatly diminished by 14 days after vaccination.

Anorexia and decreased activity are rarely observed.

Hypersensitivity reactions (e.g. gastrointestinal signs such as diarrhoea and vomiting, anaphylaxis, angioedema, dyspnoea, circulatory shock, collapse) may occur rarely. If such a reaction occurs, appropriate treatment should be administered without delay. Such reactions may evolve to a more severe condition which may be life-threatening.

Systemic reactions such as lethargy, hyperthermia and general malaise may occur very rarely.

Clinical signs of immune-mediated diseases, such as haemolytic anaemia, thrombocytopenia or polyarthritis have been reported in very rare cases.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 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.

4.8 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.

4.9 Amounts to be administered and administration route

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.

Reconstituted vaccine: pink/red, or yellowish colour with slight 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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

No other adverse reactions other than those mentioned in section 4.6 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.

4.11 Withdrawal period(s)

Not applicable.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for canidae, live and inactivated viral and inactivated bacterial vaccines.

ATC vet 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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lyophilisate:

Trometamol

Edetic Acid

Sucrose

Dextran 70

Suspension:

Sodium chloride

Potassium chloride

Potassium dihydrogen phosphate

Disodium phosphate dodecahydrate

Water for injection

6.2 Major incompatibilities

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

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.

Shelf life after reconstitution according to directions: use immediately.

6.4 Special precautions for storage

Store and transport refrigerated (2°C–8°C).

Do not freeze.

Protect from light.

6.5 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.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Zoetis Belgium SA

Rue Laid Burniat 1

1348 Louvain-la-Neuve

BELGIUM

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/14/173/001

EU/2/14/173/002

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 31/07/2014.

Date of last renewal:

10. DATE OF REVISION OF THE TEXT

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (<http://www.ema.europa.eu/>).

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

ANNEX II

- A. MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCES AND MANUFACTURER RESPONSIBLE FOR BATCH RELEASE**
- B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE**
- C. STATEMENT OF THE MRLs**

**A. MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCES AND
MANUFACTURER RESPONSIBLE FOR BATCH RELEASE**

Name and address of the manufacturer of the biological active substances

Bioveta, a.s.,
Komenského 212,
683 23 Ivanovice na Hané,
CZECH REPUBLIC

Name and address of the manufacturer responsible for batch release

Bioveta, a.s.,
Komenského 212,
683 23 Ivanovice na Hané,
CZECH REPUBLIC

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription.

C. STATEMENT OF THE MRLs

Not applicable.

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 for dogs

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose of 1 ml 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 \geq 1:51

L. interrogans serovar Canicola

ALR titre \geq 1:51

L. kirschneri serovar Grippotyphosa

ALR titre \geq 1:40

L. interrogans serovar Bratislava

ALR titre \geq 1:51

Rabies virus

\geq 2.0 IU

3. PHARMACEUTICAL FORM

Lyophilisate and suspension for suspension for injection.

4. PACKAGE SIZE

25 x 1 dose

50 x 1 dose

5. TARGET SPECIES

Dogs

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous use.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

Once reconstituted, use immediately.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated.
Do not freeze. Protect from light.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Zoetis Belgium SA
Rue Laid Burniat 1
1348 Louvain-la-Neuve
BELGIUM

16. MARKETING AUTHORISATION NUMBER(S)

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

17. MANUFACTURER'S 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 lyophilisate for dogs

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Pi

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

1 dose

4. ROUTE(S) OF ADMINISTRATION

SC

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

VIAL (1 ML SUSPENSION)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Versican Plus Pi/L4R suspension for dogs

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

L4R

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

1 ml

4. ROUTE(S) OF ADMINISTRATION

SC

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

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

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:

Zoetis Belgium SA
Rue Laid Burniat 1
1348 Louvain-la-Neuve
BELGIUM

Manufacturer responsible for batch release:

Bioveta, a.s.,
Komenského 212,
683 23, Ivanovice na Hané,
CZECH REPUBLIC

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each dose of 1 ml 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

Rabies virus, strain SAD Vnukovo-32

\geq 2.0 IU***

Adjuvant:

Aluminium hydroxide

1.8 - 2.2 mg.

* Tissue culture infectious dose 50 %.

** Antibody micro agglutination-lytic reaction.

*** International units.

Lyophilisate: spongy matter of white colour.
Suspension: pink colour with fine sediment.

4. INDICATION(S)

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. ADVERSE REACTIONS

A transient swelling (up to 5 cm) may commonly be observed at the injection site following subcutaneous administration in dogs. This can be painful, warm or reddened. Any such swelling will either have spontaneously resolved or be greatly diminished by 14 days after vaccination.

Anorexia and decreased activity are rarely observed.

Hypersensitivity reactions (e.g. gastrointestinal signs such as diarrhoea and vomiting, anaphylaxis, angioedema, dyspnoea, circulatory shock, collapse) may occur rarely. If such a reaction occurs, appropriate treatment should be administered without delay. Such reactions may evolve to a more severe condition which may be life-threatening.

Systemic reactions such as lethargy, hyperthermia and general malaise may occur very rarely.

Clinical signs of immune-mediated diseases, such as haemolytic anaemia, thrombocytopenia or polyarthritis have been reported in very rare cases.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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 inform your veterinary surgeon.

7. TARGET SPECIES

Dogs.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) 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.

Reconstituted vaccine: pink/red, or yellowish colour with slight opalescence.

10. WITHDRAWAL PERIOD(S)

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.

Use immediately after reconstitution.

12. SPECIAL WARNING(S)

Special warnings for each target species

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 use in animals:

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 animals 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 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 (symptoms, emergency procedures, antidotes):

No other adverse effects other than those mentioned under section 6 (Adverse reactions) have been 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.

Incompatibilities:

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (<http://www.ema.europa.eu/>).

15. OTHER INFORMATION

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.