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 AND OTHER 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

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 UK Limited

14. MARKETING AUTHORISATION NUMBER

Vm 42058/5086

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: Read package leaflet.

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-V Veterinary medicinal product subject to prescription

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. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Pi
1 dose

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

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

5. ROUTE(S) OF ADMINISTRATION

SC

6. 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/L4

2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

L4
1 ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

5. ROUTE(S) OF ADMINISTRATION

SC

6. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PARTICULARS TO APPEAR ON THE 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 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

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

Adjuvant:

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 the completion of 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):
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 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 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.

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

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

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBER AND PACK SIZES

Vm 42058/5086

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

November 2023

Find more product information by searching for the 'Product Information Database' or 'PID' on www.gov.uk

16. CONTACT DETAILS

Marketing authorisation holder and contact details to report suspected adverse reactions:
Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP
UK
Tel: +44 (0) 345 300 8034

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 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.

POM-V
Veterinary medicinal product subject to prescription

For animal treatment only.

Approved: 21 March 2024