

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 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):

<i>Leptospira interrogans</i> serogroup Icterohaemorrhagiae serovar Icterohaemorrhagiae strain MSLB 1089 1:51	ALR ** titre ≥
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<i>Leptospira interrogans</i> serogroup Canicola serovar Canicola, strain MSLB 1090 1:51	ALR ** titre ≥
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<i>Leptospira kirschneri</i> serogroup Grippotyphosa serovar Grippotyphosa, strain MSLB 1091 1:40	ALR ** titre ≥
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<i>Leptospira interrogans</i> serogroup Australis serovar Bratislava, strain MSLB 1088 1:51	ALR ** titre ≥
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* Tissue culture infectious dose 50%.

** Antibody micro agglutination-lytic reaction.

Adjuvant:

Aluminium hydroxide	1.8–2.2 mg.
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Excipients:

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: whitish 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 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.

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 medicinal therapy and stress.

Vaccinate healthy animals only.

4.5 Special precautions for use

Special precautions for use in animals

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.

Other precautions

Not applicable.

4.6 Adverse reactions (frequency and seriousness)

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

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 its local representative or the national competent authority via the national reporting system. See also section 16 of the package leaflet for contact details.

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 has 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 Amount(s) to be administered and administration route

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.

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

No 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 viral and inactivated bacterial vaccines.

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.

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 injections

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 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.

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

Medicines should not be disposed of via wastewater.

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 UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

8. MARKETING AUTHORISATION NUMBER

Vm 42058/5086

9. DATE OF FIRST AUTHORISATION

31 July 2014

10. DATE OF REVISION OF THE TEXT

November 2023


PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

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



Approved 14 March 2024