SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Versican Plus L4 suspension for injection for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 1 ml contains:

Active substances:

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

* Antibody micro agglutination-lytic reaction.

Adjuvant:

Aluminium hydroxide	1.8–2.2 mg.

Excipients:
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection.

The visual appearance is as follows: whitish liquid 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, 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:
4 weeks after completion of the primary course.

Duration of immunity:
At least one year following the primary vaccination course for all components of Versican Plus 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
Not applicable.

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

[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 section16 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 other than Versican Plus DHPPi and Versican Plus Pi. 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.

Vaccination against distemper, adeno, parvo and parainfluenza virus (DHPPi):
If protection against DHPPi or Pi is required, dogs can be vaccinated with two doses of Versican Plus DHPPi or Versican Plus Pi mixed with Versican Plus L4 3–4 weeks apart from 6 weeks of age:

The contents of a single vial of Versican Plus DHPPi or Versican Plus Pi should be reconstituted with the contents of a single vial of Versican Plus L4 (instead of the solvent). Once mixed, the contents of the vial should appear a whitish to yellowish colour with light opalescence (Pi/L4) or pinkish or yellowish colour with light opalescence (DHPPi/L4). The mixed vaccines should be injected immediately via the subcutaneous route.

4.9 Amount(s) to be administered and administration route

Subcutaneous use.

Dosage and route of administration:
Shake well and administer immediately the entire contents (1 ml) of the product.

Primary vaccination scheme:
Two doses of Versican Plus L4 3–4 weeks apart from 6 weeks of age.

Re-vaccination scheme:
A single dose of Versican Plus L4 to be given annually.

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

No data are available on the safety of an overdose.

4.11 Withdrawal period(s)

Not applicable.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for canidae, inactivated bacterial vaccines.

ATCvet code: QI07AB01

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

Suspension:
Sodium chloride
Potassium chloride

Potassium dihydrogen phosphate
Disodium phosphate dodecahydrate
Water for injections

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal product except those mentioned in section 4.8 above.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: 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 ml closed with a chlorobutyl rubber stopper and aluminium cap.

Pack sizes:
Plastic box containing 25 vials (1 ml).
Plastic box containing 50 vials (1 ml).

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 42058/5084

9. DATE OF FIRST AUTHORISATION

08 April 2019

10. DATE OF REVISION OF THE TEXT

June 2024

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 22 June 2024
Gavin Hall