

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Versican Plus DHPPi/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):**

|   | <b>Minimum</b>                         | <b>Maximum</b>                         |
|---|--|--|
| Canine distemper virus, strain CDV Bio 11/A             | 10 <sup>3.1</sup> TCID <sub>50</sub> * | 10 <sup>5.1</sup> TCID <sub>50</sub> * |
| Canine adenovirus Type 2, strain CAV-2 Bio 13           | 10 <sup>3.6</sup> TCID <sub>50</sub> * | 10 <sup>5.3</sup> TCID <sub>50</sub> * |
| Canine parvovirus Type 2b, strain CPV-2b Bio 12/B       | 10 <sup>4.3</sup> TCID <sub>50</sub> * | 10 <sup>6.6</sup> TCID <sub>50</sub> * |
| Canine parainfluenza Type 2 virus, strain CPIV-2 Bio 15 | 10 <sup>3.1</sup> TCID <sub>50</sub> * | 10 <sup>5.1</sup> TCID <sub>50</sub> * |

#### **Suspension (inactivated):**

|  |                    |
|--|--------------------|
| <i>Leptospira interrogans</i> serogroup Icterohaemorrhagiae serovar Icterohaemorrhagiae strain MSLB 1089 | ALR** titre ≥ 1:51 |
| <i>Leptospira interrogans</i> serogroup Canicola serovar Canicola, strain MSLB 1090                      | ALR** titre ≥ 1:51 |
| <i>Leptospira kirschneri</i> serogroup Grippotyphosa serovar Grippotyphosa, strain MSLB 1091             | ALR** titre ≥ 1:40 |
| <i>Leptospira interrogans</i> 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.

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 mortality and clinical signs caused by canine distemper virus,
- to prevent mortality and clinical signs caused by canine adenovirus type 1,
- to prevent clinical signs and reduce viral excretion caused by canine adenovirus type 2,
- to prevent clinical signs, leucopenia and viral excretion caused by canine parvovirus,
- 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 the first vaccination for CDV, CAV, CPV,
- 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 canine distemper virus, canine adenovirus type 1, canine adenovirus type 2 and canine parvovirus. The duration of immunity against CAV-2 was not established by challenge. It was shown that 3 years after the vaccination CAV-2 antibodies are still present. Protective immune response against CAV-2 associated respiratory disease is considered to last at least 3 years. At least one year following the primary vaccination course for canine parainfluenza virus and *Leptospira* components.

### 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.

Immunological responses to the CDV, CAV and CPV components of the vaccine may be delayed due to maternally derived antibody interference. However, the vaccine has been proven to be protective against virulent challenge in the presence of maternally derived antibodies to CDV, CAV and CPV at levels equal or higher to those likely to be encountered under field conditions. In situations where very high maternally derived antibody levels are expected, the vaccination protocol should be planned accordingly.

Vaccinate healthy animals only.

#### 4.5 Special precautions for use

##### Special precautions for use in animals

The live attenuated virus vaccine strains CAV-2, CPiV and CPV-2b may be shed by vaccinated dogs following vaccination, shedding of CPV has been shown for up to 10 days. However, due to the low pathogenicity of these strains, it is not necessary to keep vaccinated dogs separated from non-vaccinated dogs and domestic cats. The vaccine virus strain CPV-2b has not been tested in other carnivores (except dogs and domestic cats) that are known to be susceptible to canine parvoviruses and therefore vaccinated dogs should be separated from them after vaccination.

##### 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<br>(1 to 10 animals / 100 animals treated):                   | Injection site swelling <sup>1</sup>  |
| Rare<br>(1 to 10 animals / 10 000 animals treated):                  | Injection site lump, Injection site mass, Injection site nodule<br>Hypersensitivity reaction <sup>2</sup> (anaphylaxis, angioedema, circulatory shock, collapse, diarrhoea, dyspnoea, vomiting)<br>Anorexia, Decreased activity |
| Very rare<br>(<1 animal / 10 000 animals treated, including isolated | Hyperthermia, Lethargy, Malaise<br>Immune mediated haemolytic anaemia,<br>Immune mediated haemolytic  |

|           |   |
|-----------|---|
| reports): | thrombocytopenia, Immune mediated polyarthritis |
|-----------|---|

<sup>1</sup>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.

<sup>2</sup>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 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.

##### Rabies:

If protection against Rabies is required:

First dose: Versican Plus DHPPI/L4 from 8–9 weeks of age.

Second dose: Versican Plus DHPPI/L4R 3–4 weeks later but not before 12 weeks of age.

The efficacy of the rabies fraction is proven after a single dose from 12 weeks of age in laboratory studies. 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 UK, 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  $\geq 0.5$  IU/ml, which is generally regarded as sufficiently protective and that they meet the travel test requirements (antibody titres  $\geq 0.5$  IU/ml).

In case of need, dogs younger than 8 weeks can be vaccinated as safety of Versican Plus DHPPI/L4R has been demonstrated in 6-week old dogs.

#### 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 content (1 ml) of the reconstituted product. Appearance of the reconstituted vaccine: pinkish or yellowish colour with light opalescence.

##### Primary vaccination scheme:

Two doses of Versican Plus DHPi/L4 3–4 weeks apart from 6 weeks of age.

##### Re-vaccination scheme:

A single dose of Versican Plus DHPi/L4 should be given every 3 years. Annual re-vaccination is required for Parainfluenza 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 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:** QI07AI02

The vaccine is intended for the active immunisation of healthy puppies and dogs against diseases caused by canine distemper virus, canine parvovirus, canine adenovirus type 1 and 2, 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 42058/5083

## **9. DATE OF FIRST AUTHORISATION**

07 May 2014

## **10. DATE OF REVISION OF THE TEXT**

April 2026

### **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](http://www.gov.uk).

*Gavin Hall*  
Approved: 21 April 2026