

**ANNEX I**  
**SUMMARY OF PRODUCT CHARACTERISTICS**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Versican Plus DHPPi/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):**

	<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
Rabies virus, strain SAD Vnukovo-32	≥ 5 IU***

\* Tissue culture infectious dose 50%.

\*\* Antibody micro agglutination-lytic reaction.

\*\*\* International units.

### Adjuvant:

Aluminium hydroxide 1.8–2.2 mg.

### Excipients:

<b>Qualitative composition of excipients and other constituents</b>
<b>Lyophilisate:</b>
Trometamol
Edetic Acid
Sucrose
Dextran 70
<b>Suspension:</b>
Sodium chloride
Potassium chloride
Potassium dihydrogen phosphate
Disodium phosphate dodecahydrate
Water for injections

The visual appearance is as follows:

Lyophilisate: spongy matter of white colour.

Suspension: pink colour with fine sediment.

### **3. CLINICAL INFORMATION**

#### **3.1 Target species**

Dogs.

#### **3.2 Indications for use for each target species**

Active immunisation of dogs from 8–9 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,
- 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 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, canine parvovirus and rabies. 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. Duration of immunity for rabies was demonstrated after one vaccination at 12 weeks of age.

#### **3.3 Contraindications**

None.

#### **3.4 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 drug 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.

### 3.5 Special precautions for use

#### Special precautions for safe use in the target species:

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 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.

### 3.6 Adverse events

Dogs:

Common (1 to 10 animals / 100 animals treated):	injection site swelling <sup>1</sup>
Rare (1 to 10 animals / 10,000 animals treated):	hypersensitivity reaction <sup>2</sup> (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

<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 the national competent authority via the national reporting system. See the package leaflet for respective contact details.

### **3.7 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.

### **3.8 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.

### **3.9 Administration routes and dosage**

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.

Appearance of the reconstituted vaccine: pink/red, or yellowish colour with light opalescence.

#### Primary vaccination scheme:

Two doses of Versican Plus DHPPi/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 DHPPi/L4. In this case the second vaccination with Versican Plus DHPPi/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  $\geq 0.5$  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 this product has been demonstrated in 6-week old dogs.

#### Re-vaccination scheme:

A single dose of Versican Plus DHPPi/L4R 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.

### **3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)**

No adverse events other than those mentioned in section 3.6 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.

### **3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance**

Official control authority batch release is required for this product.

### **3.12 Withdrawal periods**

Not applicable.

## **4. IMMUNOLOGICAL INFORMATION**

### **4.1 ATCvet code: QI07AJ06.**

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, *Leptospira interrogans* serogroup Icterohaemorrhagiae serovar Icterohaemorrhagiae, and rabies virus.

## **5. PHARMACEUTICAL PARTICULARS**

### **5.1 Major incompatibilities**

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

### **5.2 Shelf life**

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.  
Shelf life after reconstitution according to directions: use immediately.

### **5.3 Special precautions for storage**

Store and transport refrigerated (2 °C – 8 °C).  
Do not freeze.  
Protect from light.

### **5.4 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.

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

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

**6. NAME OF THE MARKETING AUTHORISATION HOLDER**

Zoetis Belgium

**7. MARKETING AUTHORISATION NUMBER(S)**

EU/2/14/163/001

EU/2/14/163/002

**8. DATE OF FIRST AUTHORISATION**

Date of first authorisation: 07/05/2014.

**9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS**

**10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS**

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database.

## **ANNEX II**

### **OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION**

None.



**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 DHPPi/L4R lyophilisate and suspension for suspension for injection.

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each dose of 1 ml contains:

**Active substances:****Lyophilisate (live attenuated):**

	<b>Minimum</b>	<b>Maximum</b>
Canine distemper virus	10 <sup>3.1</sup> TCID <sub>50</sub>	10 <sup>5.1</sup> TCID <sub>50</sub>
Canine adenovirus Type 2	10 <sup>3.6</sup> TCID <sub>50</sub>	10 <sup>5.3</sup> TCID <sub>50</sub>
Canine parvovirus Type 2b	10 <sup>4.3</sup> TCID <sub>50</sub>	10 <sup>6.6</sup> TCID <sub>50</sub>
Canine parainfluenza virus Type 2	10 <sup>3.1</sup> TCID <sub>50</sub>	10 <sup>5.1</sup> TCID <sub>50</sub>

**Suspension (inactivated):**

<i>L. interrogans</i> serovar Icterohaemorrhagiae	ALR titre ≥ 1:51
<i>L. interrogans</i> serovar Canicola	ALR titre ≥ 1:51
<i>L. kirschneri</i> serovar Grippotyphosa	ALR titre ≥ 1:40
<i>L. interrogans</i> serovar Bratislava	ALR titre ≥ 1:51
Rabies virus	≥ 5 IU

**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 Belgium

**14. MARKETING AUTHORISATION NUMBERS**

EU/2/14/163/001

EU/2/14/163/002

**15. 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 DHPPi/L4R



**2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES**

DHPPi  
1 dose

**3. BATCH NUMBER**

Lot {number}

**4. EXPIRY DATE**

Exp. {mm/yyyy}

Once reconstituted use immediately.

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**  
**VIAL (1 ML SUSPENSION)**

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

Versican Plus DHPPi/L4R



**2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES**

L4R  
1 ml

**3. BATCH NUMBER**

Lot {number}

**4. EXPIRY DATE**

Exp. {mm/yyyy}

**B. PACKAGE LEAFLET**

## PACKAGE LEAFLET

### 1. Name of the veterinary medicinal product

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

### 2. 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
Rabies virus, strain SAD Vnukovo-32	≥ 5 IU***

\* Tissue culture infectious dose 50%.

\*\* Antibody micro agglutination-lytic reaction.

\*\*\* International units.

#### Adjuvant:

Aluminium hydroxide 1.8–2.2 mg.

The visual appearance is as follows:

Lyophilisate: spongy matter of white colour.

Suspension: pink colour with fine sediment.

### 3. Target species

Dogs.

### 4. Indications for use

Active immunisation of dogs from 8–9 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,
- 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 the first vaccination for CDV, CAV, CPV,
- 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 canine distemper virus, canine adenovirus type 1, canine adenovirus type 2, canine parvovirus and rabies. 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. Duration of immunity for rabies was demonstrated after one vaccination at 12 weeks of age.

## **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 drug 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.

#### Special precautions for safe use in the target species:

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 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.

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:

No adverse events other than those mentioned in section 7 (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.

Special restrictions for use and special conditions for use:

Official control authority batch release is required for this product.

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 <sup>1</sup>
Rare (1 to 10 animals / 10,000 animals treated):
hypersensitivity reaction <sup>2</sup> (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

<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 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 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 DHPPi/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 DHPPi/L4. In this case the second vaccination with Versican Plus DHPPi/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  $\geq 0.5$  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 this product has been demonstrated in 6-week old dogs.

### Re-vaccination scheme:

A single dose of Versican Plus DHPPi/L4R 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.

## **9. Advice on correct administration**

Aseptically reconstitute the lyophilisate with suspension. Shake well and administer immediately the entire content (1 ml) of the reconstituted product.

Appearance of the reconstituted vaccine: pink/red, or 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 or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

## **13. Classification of veterinary medicinal products**

Veterinary medicinal product subject to prescription.

## **14. Marketing authorisation numbers and pack sizes**

EU/2/14/163/001-002

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**

Detailed information on this veterinary medicinal product is available in the Union Product Database.

## **16. Contact details**

Marketing authorisation holder and contact details to report suspected adverse reactions:

Zoetis Belgium  
Rue Laid Burniat 1  
1348 Louvain-La-Neuve  
Belgium

**België/Belgique/Belgien**  
Tél/Tel: +32 (0) 800 99 189  
[pharmvig-belux@zoetis.com](mailto:pharmvig-belux@zoetis.com)

**Република България**  
Тел: +359 888 51 30 30  
[zoetisromania@zoetis.com](mailto:zoetisromania@zoetis.com)

**Česká republika**  
Tel: +420 257 101 111  
[infovet.cz@zoetis.com](mailto:infovet.cz@zoetis.com)

**Danmark**  
Tlf: +45 70 20 73 05  
[adr.scandinavia@zoetis.com](mailto:adr.scandinavia@zoetis.com)

**Lietuva**  
Tel: +370 610 05088  
[zoetis.lithuania@zoetis.com](mailto:zoetis.lithuania@zoetis.com)

**Luxembourg/Luxemburg**  
Tél/Tel: +32 (2) 746 80 11  
[pharmvig-belux@zoetis.com](mailto:pharmvig-belux@zoetis.com)

**Magyarország**  
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## **17. Other information**

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, *Leptospira interrogans* serogroup Icterohaemorrhagiae serovar Icterohaemorrhagiae, and rabies virus.