

**ANNEX I**  
**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 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.

## 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.

#### **4.6 Adverse reactions (frequency and seriousness)**

A transient swelling (up to 5 cm) may commonly be observed at the injection site following subcutaneous administration in dogs. This can be painful, warm or reddened. Any such swelling will either have spontaneously resolved or be greatly diminished by 14 days after vaccination.

Anorexia and decreased activity are rarely observed.

Hypersensitivity reactions (e.g. gastrointestinal signs such as diarrhoea and vomiting, anaphylaxis, angioedema, dyspnoea, circulatory shock, collapse) may occur rarely. If such a reaction occurs, appropriate treatment should be administered without delay. Such reactions may evolve to a more severe condition which may be life-threatening.

Systemic reactions such as lethargy, hyperthermia and general malaise may occur very rarely.

Clinical signs of immune-mediated diseases, such as haemolytic anaemia, thrombocytopenia or polyarthritis have been reported in very rare cases.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

#### **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 have 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 Amounts to be administered and administration route**

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.

Reconstituted vaccine: pinkish or yellowish colour with slight opalescence.

#### Primary vaccination scheme:

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

#### 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 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 Versican Plus DHPPi/L4R has been demonstrated in 6 weeks old dogs.

#### Re-vaccination scheme:

A single dose of Versican Plus DHPPi/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 other 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.  
ATC vet 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 injection

### **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**

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 Belgium SA  
Rue Laid Burniat 1  
1348 Louvain-la-Neuve  
BELGIUM

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

EU/2/14/164/001  
EU/2/14/164/002

**9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 07/05/2014.  
Date of last renewal: 08/04/2019.

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

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (<http://www.ema.europa.eu/>).

**PROHIBITION OF SALE, SUPPLY AND/OR USE**

Not applicable.

**ANNEX II**

- A. MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCES AND MANUFACTURER RESPONSIBLE FOR BATCH RELEASE**
- B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE**
- C. STATEMENT OF THE MRLs**



**A. MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCES AND  
MANUFACTURER RESPONSIBLE FOR BATCH RELEASE**

Name and address of the manufacturer of the biological active substances

Bioveta, a.s.,  
Komenského 212,  
683 23 Ivanovice na Hané,  
CZECH REPUBLIC

Name and address of the manufacturer responsible for batch release

Bioveta, a.s.,  
Komenského 212,  
683 23 Ivanovice na Hané,  
CZECH REPUBLIC

**B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE**

Veterinary medicinal product subject to prescription.

**C. STATEMENT OF THE MRLs**

Not applicable.

**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/L4 lyophilisate and suspension for suspension for injection for dogs

**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	$10^{3.1}$ TCID <sub>50</sub>	$10^{5.1}$ TCID <sub>50</sub>
Canine adenovirus Type 2	$10^{3.6}$ TCID <sub>50</sub>	$10^{5.3}$ TCID <sub>50</sub>
Canine parvovirus Type 2b	$10^{4.3}$ TCID <sub>50</sub>	$10^{6.6}$ TCID <sub>50</sub>
Canine parainfluenza virus Type 2	$10^{3.1}$ TCID <sub>50</sub>	$10^{5.1}$ TCID <sub>50</sub>

**Suspension (inactivated):**

<i>L. interrogans</i> serovar Icterohaemorrhagiae	ALR titre $\geq$ 1:51
<i>L. interrogans</i> serovar Canicola	ALR titre $\geq$ 1:51
<i>L. kirschneri</i> serovar Grippotyphosa	ALR titre $\geq$ 1:40
<i>L. interrogans</i> serovar Bratislava	ALR titre $\geq$ 1:51

**3. PHARMACEUTICAL FORM**

Lyophilisate and suspension for suspension for injection.

**4. PACKAGE SIZE**

25 x 1 dose  
50 x 1 dose

**5. TARGET SPECIES**

Dogs

**6. INDICATION(S)**

Read the package leaflet before use.

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

Subcutaneous use.  
Read the package leaflet before use.

**8. WITHDRAWAL PERIOD(S)**

**9. SPECIAL WARNING(S), IF NECESSARY**

Read the package leaflet before use.

**10. EXPIRY DATE**

EXP {month/year}  
Once reconstituted, use immediately.

**11. SPECIAL STORAGE CONDITIONS**

Store and transport refrigerated.  
Do not freeze. Protect from light.

**12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY**

Disposal: read package leaflet.

**13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE**

For animal treatment only. To be supplied only on veterinary prescription.

**14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”**

Keep out of the sight and reach of children.

**15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

Zoetis Belgium SA  
Rue Laid Burniat 1  
1348 Louvain-la-Neuve  
BELGIUM

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

EU/2/14/164/001  
EU/2/14/164/002

**17. MANUFACTURER'S BATCH NUMBER**

Lot {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

**VIALS (1 DOSE LYOPHILISATE)**

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

Versican Plus DHPPi/L4 lyophilisate for dogs

**2. QUANTITY OF THE ACTIVE SUBSTANCE(S)**

DHPPi

**3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES**

1 dose

**4. ROUTE(S) OF ADMINISTRATION**

SC

**5. WITHDRAWAL PERIOD(S)**

**6. BATCH NUMBER**

Lot {number}

**7. EXPIRY DATE**

EXP {month/year}

**8. 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 DHPPi/L4 suspension for dogs

**2. QUANTITY OF THE ACTIVE SUBSTANCE(S)**

L4

**3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES**

1 ml

**4. ROUTE(S) OF ADMINISTRATION**

SC

**5. WITHDRAWAL PERIOD(S)**

**6. BATCH NUMBER**

Lot {number}

**7. EXPIRY DATE**

EXP {month/year}

**8. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

For animal treatment only.



## **B. PACKAGE LEAFLET**

## PACKAGE LEAFLET:

### Versican Plus DHPPi/L4 lyophilisate and suspension for suspension for injection for dogs

#### 1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

##### Marketing authorisation holder:

Zoetis Belgium SA  
Rue Laid Burniat 1  
1348 Louvain-la-Neuve  
BELGIUM

##### Manufacturer responsible for batch release:

Bioveta, a.s.,  
Komenského 212,  
683 23 Ivanovice na Hané,  
CZECH REPUBLIC

#### 2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Versican Plus DHPPi/L4 lyophilisate and suspension for suspension for injection for dogs

#### 3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

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

##### **Adjuvant:**

Aluminium hydroxide 1.8–2.2 mg.

\* Tissue culture infectious dose 50%.

\*\* Antibody micro agglutination-lytic reaction.

Lyophilisate: spongy matter of white colour.

Suspension: whitish colour with fine sediment.

#### **4. INDICATION(S)**

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 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 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.

#### **5. CONTRAINDICATIONS**

None.

#### **6. ADVERSE REACTIONS**

A transient swelling (up to 5 cm) may commonly be observed at the injection site following subcutaneous administration in dogs. This can be painful, warm or reddened. Any such swelling will either have spontaneously resolved or be greatly diminished by 14 days after vaccination.

Anorexia and decreased activity are rarely observed.

Hypersensitivity reactions (e.g. gastrointestinal signs such as diarrhoea and vomiting, anaphylaxis, angioedema, dyspnoea, circulatory shock, collapse) may occur rarely. If such a reaction occurs,

appropriate treatment should be administered without delay. Such reactions may evolve to a more severe condition, which may be life-threatening.

Systemic reactions such as lethargy, hyperthermia and general malaise may occur very rarely.

Clinical signs of immune-mediated diseases, such as haemolytic anaemia, thrombocytopenia or polyarthritis have been reported in very rare cases.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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 inform your veterinary surgeon.

## **7. TARGET SPECIES**

Dogs.

## **8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION**

Subcutaneous use.

### Primary vaccination scheme:

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

### 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 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 Versican Plus DHPPi/L4R has been demonstrated in 6 weeks old dogs.

### Re-vaccination scheme:

A single dose of Versican Plus DHPPi/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.

## **9. ADVICE ON CORRECT ADMINISTRATION**

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

Reconstituted vaccine: pinkish, or yellowish colour with slight opalescence.

## **10. WITHDRAWAL PERIOD(S)**

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.

Use immediately after reconstitution.

## **12. SPECIAL WARNING(S)**

### 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 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 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.

### Pregnancy 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 (symptoms, emergency procedures, antidotes):

No other adverse effects other than those mentioned under section 6 (Adverse reactions) have been 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.

Incompatibilities:

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

**13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY**

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

**14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED**

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (<http://www.ema.europa.eu/>).

**15. OTHER INFORMATION**

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.