ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS
1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 1 ml contains:

**Active substances:**

<table>
<thead>
<tr>
<th>Lyophilisate (live attenuated)</th>
<th>Minimum</th>
<th>Maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Canine distemper virus, strain CDV Bio 11/A</td>
<td>$10^{3.1}$ TCID$_{50}^*$</td>
<td>$10^{3.1}$ TCID$_{50}$</td>
</tr>
<tr>
<td>Canine adenovirus type 2, strain CAV-2 Bio 13</td>
<td>$10^{3.6}$ TCID$_{50}^*$</td>
<td>$10^{5.3}$ TCID$_{50}$</td>
</tr>
<tr>
<td>Canine parvovirus type 2b, strain CPV-2b Bio 12/B</td>
<td>$10^{4.3}$ TCID$_{50}^*$</td>
<td>$10^{6.6}$ TCID$_{50}$</td>
</tr>
<tr>
<td>Canine parainfluenza type 2 virus, strain CPiV-2 Bio 15</td>
<td>$10^{3.1}$ TCID$_{50}^*$</td>
<td>$10^{5.1}$ TCID$_{50}$</td>
</tr>
</tbody>
</table>

**Solvent (inactivated)**

*Leptospira interrogans* serogroup Icterohaemorrhagiae

serovar Icterohaemorrhagiae strain MSLB 1089

*Leptospira interrogans* serogroup Canicola

serovar Canicola, strain MSLB 1090

*Leptospira kirschneri* serogroup Grippotyphosa

serovar Grippotyphosa, strain MSLB 1091

*Leptospira interrogans* serogroup Australis

serovar Bratislava, strain MSLB 1088

Inactivated rabies virus, strain SAD Vnukovo-32

**Adjuvant:**

Aluminium hydroxide

1.8–2.2 mg.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for injection.

The visual appearance is as follows:

Lyophilisate: spongy matter of white colour.

Solvent: pink 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 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 Icterohaemorrhagie serovar Icterohaemorrhagiae,
- to prevent clinical signs and reduce infection and urinary excretion caused by *L.interrogans* 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 CDV, CAV-1, CAV-2 and CPV. 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 CPiV, *Leptospira* components and rabies. Duration of immunity for rabies was demonstrated after one vaccination at 12 weeks of age.

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.

4.5 Special precautions for use

Special precautions for use in animals

Vaccinate healthy animals only.
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 animals 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. The vaccine virus strain CPV-2b has not been tested in domestic cats and other carnivores (except dogs) that are known to be susceptible to canine paroviruses. Therefore vaccinated dogs should be separated from other canine and feline species 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)

Following subcutaneous administration in dogs a transient swelling (up to 5 cm) may commonly be observed at the injection site. These can occasionally be painful, warm or reddened. Any such swelling will either have spontaneously resolved or be greatly diminished by 14 days after vaccination. In rare cases gastrointestinal signs such as diarrhoea and vomiting or anorexia and decreased activity are possible.

As with any vaccine rare, occasional hypersensitivity reactions may occur. If such a reaction occurs, appropriate treatment should be administered without delay.

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

- very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

4.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Therefore the use is not recommended during pregnancy and lactation.

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 by the veterinarian.

4.9 Amounts to be administered and administration route

Subcutaneous use.

Dose and route of administration: Aseptically reconstitute the lyophilisate with the solvent. Shake well and administer immediately the entire content (1 ml) of the reconstituted product.

Reconstituted vaccine: pink/red, or yellowish colour with slight 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. Another 17% did not show the 0.5 IU/ml rabies antibody titre required by some non-EU countries to travel in. In case of travelling to risk areas or for travel outside the EU veterinary surgeons may wish to use a two dose primary course including rabies or give an additional rabies vaccination after 12 weeks.

In case of need, dogs younger than 8 weeks can be vaccinated as safety of this product has been demonstrated in 6 weeks 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, Leptospira components and rabies therefore a single dose of compatible vaccine Versican Plus Pi/L4R 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. The pain was transient and subsided without requiring any therapy.

4.11 Withdrawal period(s)
Not applicable.

5. IMMUNOLOGICAL PROPERTIES
Pharmacotherapeutic group: Immunologicals for canidae, live and inactivated viral and inactivated bacterial vaccines.
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 interrogans serogroup Grippotyphosa serovar Grippotyphosa, Leptospira interrogans serogroup Icterohaemorrhagiae serovar Icterohaemorrhagiae, and rabies virus.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Lyophilisate:
Trometamol
Edetic Acid
Sucrose
Dextran 70

**Solvent:**
Sodium chloride  
Potassium chloride  
Potassium dihydrogen phosphate  
Disodium phosphate dodecahydrate  
Water for injection

### 6.2 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 solvent closed with a chlorobutyl rubber stopper and aluminium cap.

Pack sizes:
Plastic box containing 25 vials of lyophilisate and 25 vials of solvent.  
Plastic box containing 50 vials of lyophilisate and 50 vials of solvent.

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/2/14/163/001
9. **DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 07/05/2014

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


**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

The printed package leaflet of the medicinal product must state the name and address of the manufacturer responsible for the release of the concerned batch.

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/L4R lyophilisate and solvent for suspension for injection for dogs

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Per dose (1 ml):

<table>
<thead>
<tr>
<th>Lyophilisate (live attenuated)</th>
<th>Minimum</th>
<th>Maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Canine distemper virus</td>
<td>$10^{3.1}$ TCID$_{50}$</td>
<td>$10^{3.1}$ TCID$_{50}$</td>
</tr>
<tr>
<td>Canine adenovirus type 2</td>
<td>$10^{3.6}$ TCID$_{50}$</td>
<td>$10^{5.3}$ TCID$_{50}$</td>
</tr>
<tr>
<td>Canine parovirus type 2b</td>
<td>$10^{3.3}$ TCID$_{50}$</td>
<td>$10^{6.6}$ TCID$_{50}$</td>
</tr>
<tr>
<td>Canine parainfluenza virus type 2</td>
<td>$10^{3.1}$ TCID$_{50}$</td>
<td>$10^{6.1}$ TCID$_{50}$</td>
</tr>
</tbody>
</table>

Solvent (inactivated)

- *L.interrogans* serovar Icterohaemorrhagiae
  - ALR titre $\geq 1:51$
- *L.interrogans* serovar Canicola
  - ALR titre $\geq 1:51$
- *L. kirschneri* serovar Grippotyphosa
  - ALR titre $\geq 1:40$
- *L. interrogans* serovar Bratislava
  - ALR titre $\geq 1:51$
- Inactivated rabies virus
  - $\geq 2.0$ IU

3. PHARMACEUTICAL FORM

Lyophilisate and solvent 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

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/2/14/163/001
EU/2/14/163/002
17. MANUFACTURER’S BATCH NUMBER

Lot {number}
<table>
<thead>
<tr>
<th>MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vial (1 dose lyophilisate)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>1. NAME OF THE VETERINARY MEDICINAL PRODUCT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Versican Plus DHPPi/L4R lyophilisate for dogs</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2. QUANTITY OF THE ACTIVE SUBSTANCE(S)</th>
</tr>
</thead>
<tbody>
<tr>
<td>DHPPi</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 dose</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>4. ROUTE(S) OF ADMINISTRATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>SC</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>5. WITHDRAWAL PERIOD</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>6. BATCH NUMBER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lot</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>7. EXPIRY DATE</th>
</tr>
</thead>
<tbody>
<tr>
<td>EXP</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>8. THE WORDS “FOR ANIMAL TREATMENT ONLY”</th>
</tr>
</thead>
<tbody>
<tr>
<td>For animal treatment only.</td>
</tr>
</tbody>
</table>
**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

**Vial (1 ml solvent)**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1.</strong></td>
<td><strong>NAME OF THE VETERINARY MEDICINAL PRODUCT</strong></td>
</tr>
<tr>
<td> </td>
<td>Versican Plus DHPPi/L4R solvent for dogs</td>
</tr>
<tr>
<td><strong>2.</strong></td>
<td><strong>QUANTITY OF THE ACTIVE SUBSTANCE(S)</strong></td>
</tr>
<tr>
<td> </td>
<td>L4R</td>
</tr>
<tr>
<td><strong>3.</strong></td>
<td><strong>CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES</strong></td>
</tr>
<tr>
<td> </td>
<td>1 ml</td>
</tr>
<tr>
<td><strong>4.</strong></td>
<td><strong>ROUTE(S) OF ADMINISTRATION</strong></td>
</tr>
<tr>
<td> </td>
<td>SC</td>
</tr>
<tr>
<td><strong>5.</strong></td>
<td><strong>WITHDRAWAL PERIOD</strong></td>
</tr>
<tr>
<td><strong>6.</strong></td>
<td><strong>BATCH NUMBER</strong></td>
</tr>
<tr>
<td> </td>
<td>Lot</td>
</tr>
<tr>
<td><strong>7.</strong></td>
<td><strong>EXPIRY DATE</strong></td>
</tr>
<tr>
<td> </td>
<td>EXP</td>
</tr>
<tr>
<td><strong>8.</strong></td>
<td><strong>THE WORDS “FOR ANIMAL TREATMENT ONLY”</strong></td>
</tr>
<tr>
<td> </td>
<td>For animal treatment only.</td>
</tr>
</tbody>
</table>
B. PACKAGE LEAFLET
PACKAGE LEAFLET FOR:
Versican Plus DHPPi/L4R lyophilisate and solvent 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/L4R lyophilisate and solvent for suspension for injection for dogs

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)
Per 1 ml dose:

Active substances:

<table>
<thead>
<tr>
<th>Lyophilisate (live attenuated)</th>
<th>Minimum</th>
<th>Maximum</th>
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<td>$10^{3.1} \text{ TCID}_{50}$*</td>
<td>$10^{5.1} \text{ TCID}_{50}$</td>
</tr>
<tr>
<td>Canine adenovirus type 2, strain CAV-2 Bio 13</td>
<td>$10^{3.6} \text{ TCID}_{50}$*</td>
<td>$10^{5.3} \text{ TCID}_{50}$</td>
</tr>
<tr>
<td>Canine parvovirus type 2b, strain CPV-2b Bio 12/B</td>
<td>$10^{4.3} \text{ TCID}_{50}$*</td>
<td>$10^{6.6} \text{ TCID}_{50}$</td>
</tr>
<tr>
<td>Canine parainfluenza type 2 virus, strain CPIV-2 Bio 15</td>
<td>$10^{3.1} \text{ TCID}_{50}$*</td>
<td>$10^{5.1} \text{ TCID}_{50}$</td>
</tr>
</tbody>
</table>

Solvent (inactivated)

* *Leptospira interrogans* serogroup Icterohaemorrhagiae
  serovar Icterohaemorrhagiae strain MSLB 1089
  **ALR** titre $\geq 1:51$

* *Leptospira interrogans* serogroup Canicola
  serovar Canicola, strain MSLB 1090
  **ALR** titre $\geq 1:51$

* *Leptospira kirschneri* serogroup Grippotyphosa
  serovar Grippotyphosa, strain MSLB 1091
  **ALR** titre $\geq 1:40$

* *Leptospira interrogans* serogroup Australis
  serovar Bratislava, strain MSLB 1088
  **ALR** titre $\geq 1:51$
  $\geq 2.0 \text{ IU}^{**}$

Adjuvant:

Aluminium hydroxide
1.8–2.2 mg.
** Tissue culture infectious dose 50%.
*** Antibody micro agglutination-lytic reaction.
**** International units.

Lyophilisate: spongy matter of white colour.
Solvent: pink colour with fine sediment.

4. **INDICATION(S)**

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 and 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.interrogans* 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 CDV, CAV-1, CAV-2 and CPV. 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 CPiV, *Leptospira* components and rabies. Duration of immunity for rabies was demonstrated after one vaccination at 12 weeks of age.

5. **CONTRAINDICATIONS**

None.

6. **ADVERSE REACTIONS**

Following subcutaneous administration in dogs a transient swelling (up to 5 cm) may commonly be observed at the injection site. These can occasionally be painful, warm or reddened. Any such swelling will either have spontaneously resolved or be greatly diminished by 14 days after vaccination. In rare cases gastrointestinal signs such as diarrhoea and vomiting or anorexia and decreased activity are possible.

As with any vaccine rare, occasional hypersensitivity reactions may occur. If such a reaction occurs, appropriate treatment should be administered without delay.
The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

If you notice any serious effects or other effects not mentioned in this package leaflet, 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/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. Another 17% did not show the 0.5 IU/ml rabies antibody titre required by some non-EU countries to travel in. In case of travelling to risk areas or for travel outside the EU veterinary surgeons may wish to use a two dose primary course including rabies or give an additional rabies vaccination after 12 weeks.

In case of need, dogs younger than 8 weeks can be vaccinated as safety of this product has been demonstrated in 6 weeks 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, Leptospira components and rabies therefore a single dose of compatible vaccine Versican Plus Pi/L4R can be used annually as required.

9. ADVICE ON CORRECT ADMINISTRATION
Aseptically reconstitute the lyophilisate with the solvent. Shake well and administer immediately the entire content (1 ml) of the reconstituted product.

Reconstituted vaccine: pink/red, or yellowish colour with slight opalescence.

10. WITHDRAWAL PERIOD
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 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:
Do not use in animals that are showing signs of rabies or that are suspected of being infected with rabies virus.

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.

Special precautions for use in animals:
Vaccinate healthy animals only.

The live attenuated virus vaccine strains CAV-2, CPiV and CPV-2b may be shed by vaccinated animals 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. The vaccine virus strain CPV-2b has not been tested in domestic cats and other carnivores (except dogs) that are known to be susceptible to canine parvoviruses. Therefore vaccinated dogs should be separated from other canine and feline species 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 and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Therefore the use is not recommended during pregnancy and lactation.

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 by the veterinarian.

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. The pain was transient and subsided without requiring any therapy.

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 product is available on the website of the European Medicines Agency (http://www.ema.europa.eu/).

15. OTHER INFORMATION

Plastic box containing 25 vials of lyophilisate and 25 vials of solvent. Plastic box containing 50 vials of lyophilisate and 50 vials of solvent.

Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

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