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.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each dose of 1 ml contains:

Active substances:

Lyophilisate (live attenuated):	**Minimum**	**Maximum**
Canine distemper virus	$10^{3.1}$ $TCID_{50}$	$10^{5.1}$ $TCID_{50}$
Canine adenovirus Type 2	$10^{3.6}$ $TCID_{50}$	$10^{5.3}$ $TCID_{50}$
Canine parvovirus Type 2b	$10^{4.3}$ $TCID_{50}$	$10^{6.6}$ $TCID_{50}$
Canine parainfluenza virus Type 2	$10^{3.1}$ $TCID_{50}$	$10^{5.1}$ $TCID_{50}$

Suspension (inactivated):	
L. interrogans serovar Icterohaemorrhagiae	ALR titre ≥ 1:51
L. interrogans serovar Canicola	ALR titre ≥ 1:51
L. kirschneri serovar Grippotyphosa	ALR titre ≥ 1:40
L. interrogans serovar Bratislava	ALR titre ≥ 1:51

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 UK Limited

14. MARKETING AUTHORISATION NUMBERS

Vm 42058/5083

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-V
Veterinary medicinal product subject to prescription

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS VIAL (1 DOSE LYOPHILISATE)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Versican Plus DHPPi/L4

2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

DHPPi
1 dose

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once reconstituted use immediately.

5. ROUTE(S) OF ADMINISTRATION

6. THE WORDS “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

2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

L4
1 ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

5. ROUTE(S) OF ADMINISTRATION

6. THE WORDS “FOR ANIMAL TREATMENT ONLY”

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. COMPOSITION

Each dose of 1 ml contains:

Active substances:

Lyophilisate (live attenuated):	**Minimum**	**Maximum**
Canine distemper virus, strain CDV Bio 11/A	$10^{3.1}$ $TCID_{50}$*	$10^{5.1}$ $TCID_{50}$*
Canine adenovirus Type 2, strain CAV-2 Bio 13	$10^{3.6}$ $TCID_{50}$*	$10^{5.3}$ $TCID_{50}$*
Canine parvovirus Type 2b, strain CPV-2b Bio 12/B	$10^{4.3}$ $TCID_{50}$*	$10^{6.6}$ $TCID_{50}$*
Canine parainfluenza Type 2 virus, strain CPiV-2 Bio 15	$10^{3.1}$ $TCID_{50}$*	$10^{5.1}$ $TCID_{50}$*

Suspension (inactivated):	
Leptospira interrogans serogroup Icterohaemorrhagiae serovar Icterohaemorrhagiae strain MSLB 1089	ALR** titre ≥ 1:51
Leptospira interrogans serogroup Canicola serovar Canicola, strain MSLB 1090	ALR** titre ≥ 1:51
Leptospira kirschneri serogroup Grippotyphosa serovar Grippotyphosa, strain MSLB 1091	ALR** titre ≥ 1:40
Leptospira interrogans serogroup Australis serovar Bratislava, strain MSLB 1088	ALR** titre ≥ 1:51

* Tissue culture infectious dose 50%.
** Antibody micro agglutination-lytic reaction.

Adjuvant:

Aluminium hydroxide 1.8–2.2 mg.

The visual appearance is as follows:
Lyophilisate: spongy matter of white colour.
Suspension: whitish colour with fine sediment.

3. TARGET SPECIES

Dogs.

4. INDICATIONS FOR USE

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, leucopoenia 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. 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 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.

Special precautions for safe use in the target species:
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 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.

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 EU/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 ≥ 0.5 IU/ml, which is generally regarded as sufficiently protective and that they meet the travel test requirements (antibody titres ≥ 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.

Overdose:
No adverse events other than those mentioned in section “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.

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[1]
Rare (1 to 10 animals / 10,000 animals treated):
hypersensitivity reaction[2] (anaphylaxis, angioedema, circulatory shock, collapse, diarrhoea, dyspnoea, vomiting) anorexia, decreased activity
Very rare (<1 animal / 10,000 animals treated, including isolated reports):
hyperthermia, lethargy, malaise immune mediated haemolytic anaemia, immune mediated haemolytic thrombocytopenia, immune mediated polyarthritis

[1]A transient swelling (up to 5 cm) which can be painful, warm or reddened. Any such swelling will either have spontaneously resolved or be greatly diminished by 14 days after vaccination.

[2]If a hypersensitivity reaction occurs, appropriate treatment should be administered without delay. Such reactions may evolve to a more severe condition which may be life-threatening.

Reporting adverse events is important. It allows continuous safety monitoring of a 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 or the local representative of 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/L4 3–4 weeks apart from 6 weeks of age.

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.

Appearance of the reconstituted vaccine: pinkish 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

Vm 42058/5083

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. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. CONTACT DETAILS

Marketing authorisation holder:
Zoetis Belgium
Rue Laid Burniat 1
1348 Louvain-La-Neuve
Belgium

Manufacturer responsible for batch release:
Bioveta a.s.
Komenskeho 212/12
683 23 Ivanovice Na Hane
Czechia

Local representatives and contact details to report suspected adverse reactions:

België/Belgique/Belgien
Zoetis Belgium
Mercuriusstraat 20
BE-1930 Zaventem
Tél/Tel: +32 (0) 800 99 189

Lietuva
Zoetis Belgium
Mercuriusstraat 20
1930 Zaventem
Belgija
Tel: +370 610 05088

Република България
Zoetis Belgium
Rue Laid Burniat 1
1348 Louvain-La-Neuve
Белгия
Тел: +359 888 51 30 30

Česká republika
Zoetis Česká republika, s.r.o.
náměstí 14. října 642/17
CZ 150 00 Praha
Tel: +420 257 101 111

Danmark
Zoetis Animal Health ApS
Øster Alle 48
DK-2100 København
Tlf: +45 70 20 73 05
adr.scandinavia@zoetis.com

Deutschland
Zoetis Deutschland GmbH
Schellingstr. 1
DE-10785 Berlin
Tel: +49 30 2020 0049
tierarzneimittelsicherheit@zoetis.com

Eesti
Zoetis Belgium
Mercuriusstraat 20
1930 Zaventem
Belgia
Tel: +370 610 05088

Ελλάδα
Zoetis Hellas S.A.
Φραγκοκκλησιάς 7, Μαρούσι
EL-15125 Αττική
Τηλ: +30 210 6791900

España
Zoetis Spain, S.L.
Parque Empresarial Vía Norte Edificio nº1,
c/ Quintanavides nº13
ES-28050 Madrid
Tel: +34 91 4191900

Luxembourg/Luxemburg
Zoetis Belgium
Mercuriusstraat 20
1930 Zaventem
Belsch
Tél/Tel: +32 (2) 746 80 11

Magyarország
Zoetis Hungary Kft.
Csörsz u. 41.
HU-1124 Budapest
Tel.: +36 1 224 5200

Malta
Agrimed Limited
Mdina Road, Zebbug ZBG 9016,
MT
Tel: +356 21 465 797

Nederland
Zoetis B.V.
Rivium Westlaan 74
NL-2909 LD Capelle aan den IJssel
Tel: +31 (0)10 714 0900

Norge
Zoetis Animal Health ApS
Øster Alle 48
DK-2100 København
Danmark
Tlf: +47 23 29 86 80
adr.scandinavia@zoetis.com

Österreich
Zoetis Österreich GmbH
Floridsdorfer Hauptstr. 1
AT-1210 Wien
Tel: +43 (0)1 2701100 100

Polska
Zoetis Polska Sp. z o.o.
ul. Postępu 17B
PL - 02-676 Warszawa
Tel.: +48 22 2234800

France
Zoetis France
10 rue Raymond David
FR-92240 Malakoff
Tél: +33 (0)800 73 00 65

Hrvatska
Zoetis B.V.
Podružnica Zagreb za promidžbu
Petra Hektorovića 2
HR-10000 Zagreb
Tel: +385 1 6441 462

Ireland
Zoetis Belgium S.A. (Irish Branch)
2nd Floor, Building 10,
Cherrywood Business Park,
Loughlinstown,
Co. Dublin,
IE – Dublin D18 T3Y1
Tel: +353 (0) 1 256 9800

Ísland
Zoetis Animal Health ApS
Øster Alle 48
DK-2100 København
Danmörku
Sími: +45 70 20 73 05
adr.scandinavia@zoetis.com

Portugal
Zoetis Portugal Lda.
Lagoas Park, Edifício 10
PT-2740-271 Porto Salvo
Tel: +351 21 042 72 00

România
Zoetis România S.R.L.
Expo Business Park, 54A Aviator
Popișteanu, Clădirea 2, Etaj 1-3, Sector 1,
București, 012095 - RO
Tel: +40785019479

Slovenija
Zoetis B.V.
Podružnica Zagreb za promidžbu
Petra Hektorovića 2,
10000 Zagreb,
Hrvaška
Tel: +385 1 6441 462

Slovenská republika
Zoetis Česká republika, s.r.o.
náměstí 14. října 642/17
150 00 Praha
Česká republika
Tel: +420 257 101 111

Italia
Zoetis Italia S.r.l.
Via Andrea Doria 41M,
IT-00192 Roma
Tel: +39 06 3366 8111

Suomi/Finland
Zoetis Finland Oy
Bulevardi 21 / SPACES
FI-00180 Helsinki/Helsingfors
Suomi/Finland
Puh/Tel: +358 10 336 7000
laaketurva@zoetis.com

Κύπρος
Zoetis Hellas S.A.
Φραγκοκκλησιάς 7, Μαρούσι
15125, Αττική
Ελλάδα
Τηλ: +30 210 6791900

Sverige
Zoetis Animal Health ApS
Øster Alle 48
DK-2100 Köpenhamn
Danmark
Tel: +46 (0) 76 760 0677
adr.scandinavia@zoetis.com

Latvija
Zoetis Belgium
Mercuriusstraat 20
1930 Zaventem
Beļģija
Tel: +370 610 05088

United Kingdom (Northern Ireland)
Zoetis Belgium S.A. (Irish Branch)
2nd Floor, Building 10,
Cherrywood Business Park,
Loughlinstown,
Co. Dublin,
IE – Dublin D18 T3Y1
Tel: +353 (0) 1 256 9800

United Kingdom (Great Britain)
Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey, KT22 7LP
UK
Tel: +44 (0) 345 300 8034

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 and *Leptospira interrogans* serogroup Icterohaemorrhagiae serovar Icterohaemorrhagiae.

Gavin Hall

Approved: 06 June 2024