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 DHP lyophilisate and solvent for suspension for injection.

2. STATEMENT OF ACTIVE 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	$10^{4.3}$ $TCID_{50}$	$10^{6.6}$ $TCID_{50}$

Solvent:
Water for injections (*Aqua ad iniectabilia*)

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
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

14. MARKETING AUTHORISATION NUMBERS

Vm 42058/3010

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 DHP

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

DHP
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 SOLVENT)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Versican Plus DHP

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Aqua ad iniectabilia
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 DHP lyophilisate and solvent 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	$10^{4.3}$ $TCID_{50}$*	$10^{6.6}$ $TCID_{50}$*

Solvent:
Water for injections (*Aqua ad iniectabilia*) 1 ml

* Tissue culture infectious dose 50%.

The visual appearance is as follows:
Lyophilisate: spongy matter of white colour.
Solvent: clear colourless liquid.

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 and
- to prevent clinical signs, leucopoenia and viral excretion caused by canine parvovirus.

Onset of immunity:
3 weeks after the first vaccination.

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.

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 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 other than Versiguard Rabies and Versican Plus L4. 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.

Leptospira:
If protection against *Leptospira* is required dogs can be vaccinated with two doses of Versican Plus DHP mixed with Versican Plus L4 3–4 weeks apart from 6 weeks of age:
The contents of a single vial of Versican Plus DHP should be reconstituted with the contents of a single vial of Versican Plus L4 (instead of the solvent). Once mixed, the contents of the vial should appear a whitish to yellowish colour with light opalescence. The mixed vaccines should be injected immediately via the subcutaneous route.

Rabies:
If protection against rabies is required:
First dose: Versican Plus DHP from 8–9 weeks of age.
Second dose: Versican Plus DHP mixed with Versiguard Rabies 3–4 weeks later, but not before 12 weeks of age.
The contents of a single vial of Versican Plus DHP should be reconstituted with the contents of a single vial of Versiguard Rabies (instead of the solvent). Once mixed, the contents of the vial should appear a pink/red or yellowish colour with light opalescence. The mixed vaccines should be injected immediately via the subcutaneous route.
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 seronegative 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 ≥ 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).

Although the efficacy of the rabies fraction has been demonstrated following administration at 12 weeks, at the discretion of the veterinary surgeon, in case of need, dogs younger than 8 weeks can be vaccinated with Versican Plus DHP mixed with Versiguard Rabies as the safety of this association 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:
Do not mix with any other veterinary medicinal product except those mentioned in section “Interaction with other medicinal products and other forms of interaction”.

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] (e.g., anaphylaxis (severe allergic reaction), angioedema (swelling under the skin), circulatory shock, collapse, dyspnoea (difficulty breathing), gastrointestinal signs (e.g., diarrhoea, vomiting)) Anorexia, decreased activity
Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Hyperthermia, lethargy, malaise

[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 DHP 3–4 weeks apart from 6 weeks of age.

Re-vaccination scheme:
A single dose of Versican Plus DHP should be given every 3 years.

9. Advice on correct administration

Aseptically reconstitute the lyophilisate with the solvent. Shake well and immediately inject the entire contents (1 ml) of the reconstituted product.

Appearance of the reconstituted vaccine: clear whitish to 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 42058/3010

Plastic box containing 25 vials (1 dose) of lyophilisate and 25 vials (1 ml) of solvent.
Plastic box containing 50 vials (1 dose) of lyophilisate and 50 vials (1 ml) of solvent.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

April 2023

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

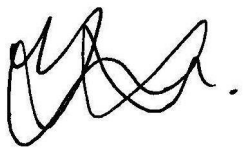
Marketing authorisation holder <and contact details to report suspected adverse reactions>:
Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

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>:>
TBC nationally if applicable.

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 and canine adenovirus types 1 and 2.



Approved: 09 June 2023