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 for dogs

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. 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)

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. SPECIFIC 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 UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

16. MARKETING AUTHORISATION NUMBER(S)

Vm 42058/5109

17. MANUFACTURER'S 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 lyophilisate for dogs

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

DHP

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 SOLVENT)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Versican Plus DHP solvent for dogs

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Aqua ad iniectabilia

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

Manufacturer responsible for batch release:

Bioveta, a.s.,
Komenského 212/12,
683 23 Ivanovice na Hané,
CZECH REPUBLIC

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Versican Plus DHP lyophilisate and solvent 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):	**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%.

Lyophilisate: spongy matter of white colour.
Solvent: clear colourless liquid.

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 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. 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.

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.

Alternatively you can report via your national reporting system {national system details}.

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

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 a slight 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 a slight 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.

Revaccination 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.

Reconstituted vaccine: whitish to yellowish colour with a 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 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 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 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.

Overdose (symptoms, emergency procedures, antidotes):
No other adverse effects other than those mentioned under “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:
Do not mix with any other veterinary medicinal product other than those mentioned above.

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 product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

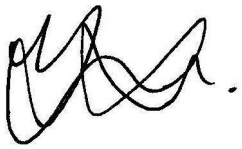
June 2023

15. OTHER INFORMATION

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.

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



Approved: 09 June 2023