1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Versican Plus DP lyophilisate and solvent for suspension for injection for dogs

2. QUALITATIVE AND QUANTITATIVE 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 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%

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: clear colourless liquid.

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 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

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 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 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 strain 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 the strain, 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.

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

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.

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 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.

4.9 Amounts to be administered and administration route

Subcutaneous use.

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

Reconstituted vaccine: Whitish to yellowish colour with light opalescence.

Primary vaccination scheme:
Two doses of Versican Plus DP 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 DP mixed with Versican Plus L4 3–4 weeks apart from 6 weeks of age:
The contents of a single vial of Versican Plus DP 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 DP from 8–9 weeks of age.
Second dose: Versican Plus DP mixed with Versiguard Rabies 3–4 weeks later, but not before 12 weeks of age.
The contents of a single vial of Versican Plus DP 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 DP 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 DP should be given every 3 years.

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 vaccines.
ATC vet code: QI07AD03.

The vaccine is intended for the active immunisation of healthy puppies and dogs against diseases caused by canine distemper virus and canine parvovirus

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lyophilisate:
Trometamol
Edetic acid (Chelaton II)
Sucrose
Dextran 70

Solvent:
Water for injections

6.2 Major incompatibilities

Do not mix with any veterinary medicinal products except those mentioned in section 4.8.

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

TBC nationally

8. MARKETING AUTHORISATION NUMBER(S)

TBC nationally

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation:
Date of last renewal:

10. DATE OF REVISION OF THE TEXT

TBC

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.