

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 1 ml contains:

Active substances:

| <u>Lyophilisate (live attenuated):</u> | Minimum | Maximum |
|---|--|--|
| Canine parainfluenza Type 2 virus, strain CPiV-2 Bio 15 | 10 ^{3.1} TCID ₅₀ * | 10 ^{5.1} TCID ₅₀ * |

Solvent:

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

* Tissue culture infectious dose 50%.

Excipients:

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 clinical signs (nasal and ocular discharge) and reduce viral excretion caused by canine parainfluenza virus.

Onset of immunity:

3 weeks after completion of the primary course.

Duration of immunity:

At least one year 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 medicinal therapy and stress.

Vaccinate healthy animals only.

4.5 Special precautions for use

Special precautions for use in animals

The live attenuated virus vaccine strain CPiV may be shed by vaccinated dogs following vaccination. However, due to the low pathogenicity of this strain, it is not necessary to keep vaccinated dogs separated from non-vaccinated dogs.

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.

Special precautions for the protection of the environment:

Not applicable

Other precautions

Not applicable.

4.6 Adverse reactions (frequency and seriousness)

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 |

¹A 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.

²If 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 veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See also section 16 of the package leaflet for contact details.

4.7 Use during pregnancy, lactation or lay

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.

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.

Leptospira:

If protection against *Leptospira* is required, dogs can be vaccinated with two doses of Versican Plus Pi mixed with Versican Plus L4 3–4 weeks apart from 6 weeks of age:

The contents of a single vial of Versican Plus Pi 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 Pi from 8–9 weeks of age.

Second dose: Versican Plus Pi mixed with Versiguard Rabies 3–4 weeks later, but not before 12 weeks of age.

The contents of a single vial of Versican Plus Pi 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 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).

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 Pi mixed with Versiguard Rabies as the safety of this association has been demonstrated in 6-week old dogs.

4.9 Amount(s) 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.

Appearance of the reconstituted vaccine: clear whitish to yellowish colour with light opalescence.

Primary vaccination scheme:

Two doses of Versican Plus Pi 3–4 weeks apart from 6 weeks of age.

Re-vaccination scheme:

A single dose of Versican Plus Pi to be given annually.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

No 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.

ATCvet code: QI07AD08

The vaccine is intended for the active immunisation of healthy puppies and dogs against disease caused by canine parainfluenza virus.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lyophilisate:

Trometamol
Edetic Acid
Sucrose
Dextran 70

Solvent:

Water for injections

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal product except those mentioned in section 4.8 above.

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 (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

Medicines should not be disposed of via wastewater.

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

8. MARKETING AUTHORISATION NUMBER

Vm 42058/5085

9. DATE OF FIRST AUTHORISATION

4th July 2014

10. DATE OF REVISION OF THE TEXT

November 2023

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

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

Approved 09 November 2023

