1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vanguard CPV solution for injection for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml dose contains:
Active substance:
Live attenuated canine Parvovirus, strain NL-35-D, low passage, minimum: $10^{7.0}$ CCID50*
*Cell culture infectious dose-50

Excipient:

Qualitative composition of excipients and other constituents
Modified Eagles medium

The liquid is slightly turbid, reddish in colour.

3. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each target species

Active immunisation of dogs to prevent mortality and clinical signs including leucopoenia and reduce viral shedding caused by canine parvovirus (types 2a, 2b and 2c).

Onset of immunity: occurs by approximately 2 weeks after the last dose of the basic vaccination scheme.
Onset of immunity: for the canine parvovirus component (type 2b) occurs 7 days after a single dose when animals are vaccinated from 9 weeks of age.

Duration of immunity: 1 year after the last dose of the basic vaccination scheme based on serology/challenge data.

3.3 Contraindications

Do not use in unhealthy animals.

3.4 Special warnings

Vaccinate healthy animals only.
Due to the presence of maternally derived antibodies, a small percentage of pups may fail to mount an adequate immune response to vaccination and may be at risk from disease when the local disease challenge is sufficiently high. The percentage of puppies that fail to mount an adequate immune response to vaccination is greater when the final vaccination is given at 10 weeks of age than it is when the final vaccination is given at 12 weeks or older, when the amounts of maternally derived antibodies will be lower. Therefore where the circumstances of the individual case permit, consideration should be given to administering the final vaccination at 12 weeks of age, even in pups that are first presented at 6 to 8 weeks of age.

3.5 Special precautions for use

Special precautions for safe use in the target species:

The canine parvovirus vaccinal strain may be shed from vaccinated animals for a number of days following vaccination. However, due to the low pathogenicity of this strain, it is not necessary to keep vaccinated animals separated from non-vaccinated animals.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In case of accidental self-injection, wash the area immediately with water. If the symptoms develop, 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.

3.6 Adverse events

Dogs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Injection site swelling[1] Anaphylactic-type reaction (e.g. vomiting)[2]

[1] Occurs 4-6 hours after vaccination which resolves after approximately 7 days.

[2] If such reaction occurs, administer adrenaline or an equivalent.

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 the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:
Do not use during pregnancy.

3.8 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. 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.

3.9 Administration routes and dosage

Dosage and route of administration:
Subcutaneous use.
Shake well and immediately inject the entire contents of the vial (1 ml).
Do not use chemically sterilised syringes or needles, as these will interfere with the effectiveness of the vaccine.

Basic Vaccination Scheme:
Puppies between 5 and 12 weeks of age:
In the absence of maternal derived antibodies (MDA): A single 1 ml dose.
In the presence of MDA or where MDA status is unknown: 2 doses at least 3 weeks apart.

The second dose should not be given until at least 10 weeks of age.
Puppies older than 12 weeks of age:
A single 1 ml dose of the veterinary medicinal product to be administered.

Re-vaccination Scheme:
A single 1 ml dose of the veterinary medicinal product to be given annually thereafter.

Annual booster vaccinations are recommended. However, should veterinary practitioners conduct a risk-benefit analysis for individual animals to determine the frequency of revaccination, they should be aware of the following information. Serological data has indicated that most dogs, when given at least the first annual booster, can maintain protective levels of immunity to the CPV component of the veterinary medicinal product for at least 4 years.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

No reactions other than those listed in Section 3.6 are observed after administration of an overdose.
No treatment is necessary in most cases of overdose.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance.

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI07AD01

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 4 years.

5.3 Special precautions for storage

Store and transport refrigerated (2 °C – 8 °C).
Do not freeze.

5.4 Nature and composition of immediate packaging

The veterinary medicinal product is filled in 1 dose vials glass type I (Ph.Eur.).
Pack contains: 1, 10, 25 or 100 vials of 1 ml.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products.

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Zoetis Belgium S.A.

7. MARKETING AUTHORISATION NUMBER(S)

VPA 10387/083/001

8. DATE OF FIRST AUTHORISATION

12/09/2014

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

21/02/2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

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