1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Vanguard CPV

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Quantity per 1 ml dose

Active substance(s):
Live attenuated canine Parvovirus, strain NL-35-D, low passage, minimum : $10^{7.0}CCID_{50}$*

*Cell culture infectious dose-50

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection.
The liquid is slightly turbid, reddish in colour.

4 CLINICAL PARTICULARS

4.1 Target Species

Dogs from 5 weeks of age.

4.2 Indications for use, specifying the target species

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

Onset of immunity occurs by approximately two 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.

The duration of immunity is 12 months, after the last dose of the basic vaccination scheme based on serology/challenge data.

4.3 Contraindications

Do not use in unhealthy animals.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

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 seperated from non-vaccinated animals.

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.

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 symptoms develop, seek medical attention showing a copy of the product literature.

4.6 Adverse reactions (frequency and seriousness)

Vaccinated dogs may have a transient swelling 4-6 hours after vaccination which resolves after approximately 7days.
If a systemic anaphylactic reaction occurs (eg vomiting), administer adrenaline or an equivalent.

4.7 Use during pregnancy, lactation or lay

Do not use during pregnancy.

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. 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

Dosage and route of administration:
Shake well and immediately inject the entire contents of the vial (1 ml) subcutaneously. 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 Vanguard CPV to be administered.

Re-vaccination Scheme:
A single 1 ml dose of Vanguard CPV 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 Vanguard CPV for at least 4 years.

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

No reactions other than those listed in Section 4.6 are observed after administration of an overdose.
No treatment is necessary in most cases of overdose.However, if systemic anaphylactic reaction occurs (e.g. vomiting), administer adrenaline or an equivalent.

4.11 Withdrawal period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for canidae, dog, live viral vaccines, canine parvovirus.

ATC vet code: QI07AD01

The vaccine is intended for the active immunization of healthy puppies and dogs against canine parvovirus disease.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Modified Eagles medium

6.2 Incompatibilities

Do not mix with any other medicinal product.

6.3 Shelf-life

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

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

The vaccine is filled in 1 dose vials glass type I (Ph.Eur.). Pack contains 1, 10, 25 or 100 vials of 1 ml liquid Vanguard CPV.
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

Dispose of waste material by boiling, incineration or immersion in an appropriatedisinfectant approved for use by the competent authorities.

7 MARKETING AUTHORISATION HOLDER

Zoetis Belgium S.A.
2nd Floor, Building 10
Cherrywood Business Park
Loughlinstown
Co Dublin
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA10387/083/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 28th May 2004
Date of last renewal: 27th May 2009

10 DATE OF REVISION OF THE TEXT

May 2017