

## 1 NAME OF THE VETERINARY MEDICINAL PRODUCT

VANGUARD CPV-L

## 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<sub>50</sub>\*

Inactivated *Leptospira canicola*, at least 40 hamster protective doses and inactivated  
*Leptospira icterohaemorrhagiae*, at least 40 hamster protective doses.

\*Cell culture infectious dose-50

For a full list of excipients see section 6.1.

## 3 PHARMACEUTICAL FORM

Solution for injection.

A clear to slightly turbid liquid.

## 4 CLINICAL PARTICULARS

### 4.1 Target Species

Dogs from 6 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) and to reduce infection caused by *Leptospira canicola* and *Leptospira icterohaemorrhagiae*.

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 separated 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 advice immediately and show the package leaflet or the label to the physician.

### **4.6 Adverse reactions (frequency and seriousness)**

Vaccinated dogs may have a transient swelling 4-6 hours after vaccination, which resolves after approximately 7 days.

In the rare event of a systemic anaphylactic reaction following vaccination, administer appropriate treatment such as adrenaline or an equivalent without delay.

#### **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 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 6 and 12 weeks of age:

Two doses of Vanguard CPV-L at least 14 days apart. The second dose should not be given until at least 10 weeks of age.

Puppies 12 weeks of age or older:

A single 1 ml dose of Vanguard CPV-L followed by a single 1 ml dose of Vanguard Lepto ciat least 14 days later.

##### Re-vaccination Scheme:

A single 1 ml dose of Vanguard CPV-L 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 re-vaccination, 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-L 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 an overdose. No treatment is necessary in most cases of overdose. However, if a 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 and inactivated bacterial vaccines, live canine parvovirus + inactivated leptospira.  
ATC vet code: QI07AI05

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

### **6 PHARMACEUTICAL PARTICULARS**

#### **6.1 List of excipients**

Modified Eagles medium

#### **6.2 Incompatibilities**

Do not mix with any other veterinary 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 VanguardCPV-L. 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 appropriate disinfectant approved for use by the competent authority.

## **7 MARKETING AUTHORISATION HOLDER**

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

## **8 MARKETING AUTHORISATION NUMBER(S)**

VPA10387/084/001

## **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 11<sup>th</sup> October 2004  
Date of last renewal: 4<sup>th</sup> November 2009

## **10 DATE OF REVISION OF THE TEXT**

May 2017