SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vanguard CPV-L

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Quantity per 1 ml dose

Active substances:
Live attenuated canine Parvovirus, strain NL-35-D, low passage, minimum titre: $10^{7.0}$ $CCID_{50}$*
Inactivated Leptospira canicola, between 420 and 740 RU**/dose
Inactivated Leptospira icterohaemorrhagiae, between 463 to 915 RU**/dose

*Cell culture infectious dose-50
** Relative units

For full list of excipients, see Section 6.1

3. PHARMACEUTICAL FORM

Solution for injection

4. CLINICAL PARTICULARS

4.1 Target species

Dogs

4.2 Indications for use, specifying the target species

Active immunisation of dogs to prevent clinical signs including leucopenia and reduce viral shedding caused by canine parvovirus (type 2a), to prevent mortality and clinical signs including leucopenia and reduce viral shedding caused by canine parvovirus (types 2b and 2c), and to reduce clinical signs and infection due to *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 at least 12 months.

4.3 Contraindications

Do not use in unhealthy animals.

4.4 Special warnings for each target species

The canine parvovirus vaccinal strains 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.

High levels of maternally derived antibodies (MDA) may interfere with the response to vaccination. Although the vaccine has been shown to be efficacious in the presence of levels of MDA that are likely to be encountered under field conditions, where for any reason it is likely that particularly high levels of MDA are present (for example against the CPV component), this should be taken into account when planning the timing of vaccinations.

4.5 Special precautions for use

i. Special precautions for use in animals

None

ii. 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 7 days.

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, expect when used with vaccines from the Vanguard range containing canine distemper virus, canine adenovirus or canine parainfluenza virus. A decision to use this vaccine before or after any other veterinary medicinal product therefore needs to be decided 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 younger than 10 weeks of age
Two doses of Vanguard CPV-L at least 14 days apart. The first dose can be given as young as 7 weeks of age. The second dose should not be given until at least 10 weeks of age.

Puppies 10 weeks of age and older
A single dose of Vanguard CPV-L, followed by a single dose of Vanguard Lepto-ci at least 14 days later

Re-vaccination Scheme:
A single dose of Vanguard CPV-L to be given annually thereafter

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

Occasional transient swellings may occur at the injection site after vaccination with an overdose.

No treatment is necessary in most cases of overdose. However, if a systemic anaphylactic reaction occurs (eg vomiting), administer adrenaline or an equivalent.

4.11 Withdrawal period

Not applicable.

5. IMMUNOLOGICAL PROPERTIES

The vaccine is intended for the active immunisation of healthy puppies and dogs against diseases caused by canine parvovirus, *Leptospira canicola* and *Leptospira icterohaemorrhagiae*.
ATC vet code: QI07AI05

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Neomycin
Gentamycin

6.2 Incompatibilities

Do not mix with any other vaccine or immunological product.

6.3 Shelf life

4 years.

6.4 Special precautions for storage

Store and transport at +2°C to +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), closed with a chlorobutyl rubber stopper and a varnished aluminium cap.

Pack contains 1, 10, 25 or 100 vials of 1 ml Vanguard™ CPV-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 authorities.

7. MARKETING AUTHORISATION HOLDER

Zoetis Belgium S.A.
2nd Floor, Building 10
Cherrywood Business Park
Loughlinstown
Dublin 18
D18 T3Y1
Ireland

8. MARKETING AUTHORISATION NUMBER

Vm 60021/3027

9. DATE OF FIRST AUTHORISATION

28 October 2005

10. DATE OF REVISION OF THE TEXT

January 2025

Gavin Hall
Approved: 14 January 2025