PARTICULARS TO APPEAR ON <THE OUTER PACKAGE> <AND> <THE IMMEDIATE PACKAGE>

Vanguard CPV-L – Booklet Label
25x 1 dose

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vanguard CPV-L

2. STATEMENT OF ACTIVE SUBSTANCES

Each vial contains 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 (Relative Units)/dose) and *Leptospira icterohaemorrhagiae* (between 463 and 915 RU/dose). Contains traces of neomycin and gentamycin.

*Cell culture infectious dose-50

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

25 x 1 ml dose Vanguard CPV-L

5. TARGET SPECIES

Dogs

6. INDICATION(S)

For the active immunisation of healthy puppies and dogs against diseases caused by canine parvovirus, *Leptospira canicola* and *Leptospira icterohaemorrhagiae*.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Give by subcutaneous injection.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

For full instructions and warnings see package insert.

10. EXPIRY DATE

Exp Date:

11. SPECIAL STORAGE CONDITIONS

Store and transport between +2°C and +8°C. Do not freeze.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

For full instructions and warnings see package insert.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.

POM-V
UK Authorised Veterinary Medicinal Product

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 60021/3027

17. MANUFACTURER'S BATCH NUMBER

Batch No:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vanguard CPV-L
1 dose

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vanguard CPV-L

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Vaccine containing modified live canine parvovirus, strain NL-35-D and inactivated *Leptospira canicola* and *L. icterohaemorrhagiae*.

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

1 dose

4. ROUTE(S) OF ADMINISTRATION

Give by SC injection

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Batch No:

7. EXPIRY DATE

Expiry date:

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.
Keep out of reach and sight of children.
Store and transport at 2-8°C.
Do not freeze.
Vm 60021/3027 POM-V

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Vanguard CPV-L

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

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

Manufacturer responsible for batch release:
Zoetis Belgium SA
Rue Laid Burniat 1
1348 Louvain-la-Neuve
Belgium

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vanguard CPV-L

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

VACCINE CONTAINING MODIFIED LIVE CANINE PARVOVIRUS STAIN NL-35-D AND INACTIVATED *LEPTOSPIRA CANICOLA* AND *LEPTOSPIRA ICTEROHAEMORRHAGIAE*

A solution for injection, each 1 ml dose containing live attenuated canine parvovirus, NL-35-D strain, low passage, minimum: $10^{7.0}$ $CCID_{50}$* inactivated *Leptospira canicola* (between 420 and 740 RU (Relative Units)) and inactivated *Leptospira icterohaemorrhagiae* (between 463 and 915 RU)).
*Cell culture infectious dose-50
Also contains traces of neomycin and gentamycin.

4. INDICATION(S)

For the 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 *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.

5. CONTRAINDICATIONS

Do not vaccinate unhealthy or pregnant animals.

6. ADVERSE REACTIONS

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.

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.

7. TARGET SPECIES

Dogs

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD 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.
See Further Information section for more detailed guidance relating to duration of immunity.

9. ADVICE ON CORRECT ADMINISTRATION

Not applicable.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of reach and sight of children.
Store and transport at +2°C - +8°C. Do not freeze.

12. SPECIAL WARNING(S)

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.

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.

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product, except 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.

Do not mix with any other vaccine or immunological product.

Operator warning:
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.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Dispose of waste material by boiling, incineration or immersion in an appropriate disinfectant in accordance with national requirements.

14. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the ‘Product Information Database’ on www.gov.uk.

15. OTHER INFORMATION

For animal treatment only.

LEGAL CATEGORY

POM-V

PACKAGE QUANTITIES

Pack contains 25 doses of Vanguard CPV-L. Packs of disposable syringes with needles are also available.

FURTHER INFORMATION

Annual booster vaccination is recommended. However, should Veterinary Surgeons conduct a risk-benefit analysis for individual animals to determine the frequency of revaccination with Vanguard CPV-L, 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 viral components of Vanguard CPV-L for up to 4 years. For further information please contact the company.

Canine parvovirus disease in kennels and pet shops is a problem of intensive husbandry and must be treated as such. Without careful professional attention to management practices in such places, successful disease control may be difficult to achieve.

When used in accordance with the recommended vaccination regime, Vanguard CPV-L can aid in the reduction of environmental contamination of canine parvovirus.

MARKETING AUTHORISATION NUMBER

Vm 60021/3027

Gavin Hall
Approved: 14 January 2025