ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box for 25 x 1 dose

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vanguard 7

2. STATEMENT OF ACTIVE SUBSTANCES

Vanguard 7 is presented in two fractions for reconstitution:
1. Vanguard DA_2Pi fraction containing live attenuated canine distemper virus, strain N-CDV ≥ $10^{3.0}$ $CCID_{50}$, canine adenovirus Type 2, strain Manhattan ≥ $10^{3.2}$ $CCID_{50}$, canine parainfluenzavirus, strain NL-CPI-5≥ $10^{6.0}$ $CCID_{50}$.

2. Vanguard CPV-L fraction containing live attenuated canine parvovirus, strain NL-35-D, low passage ≥ $10^{7.0}$ $CCID_{50}$ and an inactivated culture of *Leptospira canicola*, (between 420 and 740 RU (Relative Units)) and *Leptospira icterohaemorrhagiae*, (between 463 and 915 RU).

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for solution for injection.

4. PACKAGE SIZE

25 x 1 dose Vanguard DA_2Pi
25 x 1 ml dose Vanguard CPV-L

5. TARGET SPECIES

For dogs.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

Exp:

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated. Do not freeze.

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

Disposal: read package leaflet.

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

For animal treatment only. To be supplied only on veterinary prescription.

POM-V

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

Keep out of sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

16. MARKETING AUTHORISATION NUMBER(S)

Vm 42058/4157

17. MANUFACTURER'S BATCH NUMBER

Batch No (DA2Pi) / Batch No (CPV-L)

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial for lyophilisate (1 dose)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vanguard 7 (DA_2Pi)

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Canine distemper, CAV-2, parainfluenza vaccine.

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

1 dose

4. ROUTE(S) OF ADMINISTRATION

SC use

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Batch:

7. EXPIRY DATE

EXP:

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial for solvent (1 dose)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vanguard 7 (CPV-L)

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Canine parvovirus, *Leptospira canicola* and *L. icterohaemorrhagiae*.

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

1 dose

4. ROUTE(S) OF ADMINISTRATION

SC use

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Batch:

7. EXPIRY DATE

Expiry:

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Vanguard 7

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 UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

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 7

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

Vanguard 7 is presented as a lyophilisate and solvent for solution for injection. The two fractions are:

1. Vanguard DA_2Pi fraction containing live attenuated canine distemper virus, strain N-CDV, minimum titre: $10^{3.0}$ $CCID_{50}$*, live attenuated canine adenovirus Type 2, strain Manhattan, minimum titre: $10^{3.2}$ $CCID_{50}$*, live attenuated canine parainfluenzavirus, strain NL-CPI-5, minimum titre: $10^{6.0}$ $CCID_{50}$*.
2. Vanguard CPV-L fraction containing, live attenuated canine parvovirus, strain NL-35-D, low passage, minimum: $10^{7.0}$ $CCID_{50}$* and an inactivated culture of *Leptospira canicola*, (between 420 and 740 RU (Relative Units)) and *Leptospira icterohaemorrhagiae*, (between 463 and 915 RU).

* 50% cell culture infectious dose

4. INDICATION(S)

For the active immunisation of healthy puppies and dogs to prevent mortality and clinical signs due to canine distemper virus infections, 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), to reduce mortality and clinical signs due to canine adenovirus Type 1 infections, to reduce clinical signs and infection or excretion due to canine adenovirus Type 2 infections, to reduce clinical

signs and infection due to *Leptospira canicola* and *L. icterohaemorrhagiae* and to reduce pathological signs of disease caused by canine parainfluenza virus infections.

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 for canine distemper virus, canine parvovirus, canine adenovirus type 1 and 2 and the leptospiral components is at least 12 months. However, the duration of immunity for canine parainfluenzavirus has not been determined.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

In very rare cases, vaccinated dogs may have a transient swelling 4–6 hours after vaccination which resolves after approximately 7 days. In very rare cases, anaphylactic reaction occurs (e.g. circulatory shock/hypotension, loss of consciousness/collapse, pale mucous membrane, vomiting) may occur. If such reaction occurs, appropriate treatment (adrenaline or an equivalent) should be administered without delay.

Anorexia and ataxia have been reported very rarely.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Subcutaneous use.
Reconstitute one vial of the freeze-dried fraction (Vanguard DA_2Pi) aseptically using the contents of one vial of the liquid fraction (Vanguard CPV-L) as diluent. Shake

well and immediately inject the entire contents of the reconstituted vial (1 ml) subcutaneously.

Basic Vaccination Scheme:
Puppies younger than 10 weeks of age:
Two doses of Vanguard 7 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 7, followed by a single dose of Vanguard Lepto ci at least 14 days later.

Vanguard 7 can be used as appropriate in any vaccination programme developed using the Vanguard range of products.

Rabies:
If protection against rabies is required:
First dose: Vanguard 7 from 10 weeks of age.
Second dose: Vanguard Lepto-ci mixed with Versiguard Rabies at least 14 days later, but not before 12 weeks of age.

To mix both products, Vanguard vaccines should be reconstituted as described above. The reconstituted vial will then be well shaken and then mixed with 1 ml of Versiguard Rabies either in the Versiguard Rabies vial or the syringe. Versiguard Rabies will be well shaken before use. The mixed vaccines will be gently shaken and then administered immediately by subcutaneous injection.

The efficacy of the rabies fraction is proven after a single dose from 12 weeks of age in laboratory studies. However, in field studies 10% of seronegative dogs did not show seroconversion (>0.1 IU/ml) 3–4 weeks after single primary vaccination against rabies. Some animals may also not show titres > 0.5 IU/ml after the primary vaccination. Antibody titres drop over the course of the 3-year duration of immunity, although dogs are protected when challenged. In case of travelling to risk areas or outside the EU, veterinary surgeons may wish to give additional rabies vaccinations after 12 weeks of age to ensure that the vaccinated dogs have an antibody titre of ≥ 0.5 IU/ml, which is generally regarded as sufficiently protective and that they meet the travel test requirements (antibody titres ≥ 0.5 IU/ml).

Although the efficacy of the rabies fraction has been demonstrated following administration at 12 weeks, at the discretion of the veterinary surgeon, in case of need, dogs younger than 10 weeks can be vaccinated with Vanguard 7 mixed with Versiguard Rabies as the safety of this association has been demonstrated in 7-week-old dogs.

Re-vaccination scheme:
A single dose of Vanguard 7 should be given annually.
See Further Information section for more detailed guidance relating to duration of immunity.

9. ADVICE ON CORRECT ADMINISTRATION

Do not use chemically sterilised syringes or needles, as these will interfere with the effectiveness of the vaccine.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of sight and reach of children.
Store and transport refrigerated (2 °C – 8 °C). Do not freeze.
Shelf life after reconstitution according to directions: use immediately.

12. SPECIAL WARNING(S)

Special warnings for each target species:
Vaccinate healthy animals only.

The canine adenovirus Type 2 and canine parvovirus vaccinal strains may be shed from vaccinated animals for a number of days following vaccination. However, due to the low pathogenicity of these strains, 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.

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.

Pregnancy:
Do not use during pregnancy.

Interaction with other medicinal products and other forms of interaction:
Safety and efficacy data demonstrate that this vaccine can be administered subcutaneously in dogs on the same day as Versiguard Rabies either mixed or at different sites. The duration of immunity for Vanguard 7 when used with Versiguard Rabies has not been established.

After concurrent or mixed administration of Versiguard Rabies and Vanguard 7, vaccinated dogs may have a transient swelling (up to 6 cm) at the injection site and a

transient swelling of the sub-mandibular and/or pre-scapular lymph nodes at the injection site 4 hours after vaccination. These signs resolve within 24 hours.
Overdose (symptoms, emergency procedures, antidotes):
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.

Incompatibilities:
Do not mix with any other veterinary medicinal product other than Versiguard Rabies

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

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

November 2022

15. OTHER INFORMATION

For animal treatment only.

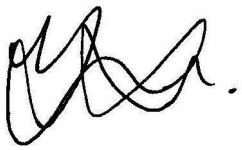
LEGAL CATEGORY
POM-V

PACKAGE QUANTITIES
Pack contains 25 doses of the Vanguard DA_2Pi freeze-dried fraction and 25 vials of the liquid 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 benefit-risk analysis for individual animals to determine the frequency of revaccination with Vanguard 7, 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 7 for up to 4 years. For further information please contact the company.
The CAV-2 strain used in Vanguard 7 has not been associated in either laboratory or field studies with corneal opacity ("blue eye") or uveitis associated with adenovirus type 1 (CAV-1).

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 7 can aid in the reduction of environmental contamination of canine parvovirus.

MARKETING AUTHORISATION NUMBER
Vm 42058/4157



Approved: 05 January 2024