SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vanguard 7

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Quantity per 1 ml dose:

Active substances:
Freeze-dried fraction: Vanguard DA_2Pi
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: $10^{6.0}$ $CCID_{50}$*

Liquid fraction: Vanguard CPV-L
Live attenuated canine parvovirus, strain NL-35-D, low passage, minimum titre: $10^{7.0}$ $CCID_{50}$*
Inactivated *Leptospira canicola*, at least 40 hamster protective doses
Inactivated *Leptospira icterohaemorrhagiae*, at least 40 hamster protective doses.

* 50% cell culture infectious dose

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for 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 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.

4.3 Contraindications

None.

4.4 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.

4.5 Special precautions for use

Special precautions for use in animals

None.

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)

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).

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

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.

4.9 Amounts to be administered and administration route

Subcutaneous use.

Dosage and route of administration:
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. 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 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.

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.

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 (e.g. vomiting), administer adrenaline or an equivalent.

4.11 Withdrawal period(s)

Not applicable.

5. IMMUNOLOGICAL PROPERTIES

The vaccine is intended for the active immunisation of healthy puppies and dogs against diseases caused by canine distemper virus, canine adenoviruses Types 1 and 2, canine parainfluenzavirus, canine parvovirus, *Leptospira canicola* and *Leptospira icterohaemorrhagiae*.

ATCvet code: QI07AI02.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

None.

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal product, except Versiguard Rabies.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale:
For the freeze-dried fraction (Vanguard DA_2Pi): 2 years
For the liquid fraction (Vanguard CPV-L): 4 years.

Shelf life after reconstitution according to directions: use immediately.

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.). Vials of the freeze-dried fraction are closed with a bromobutyl rubber stopper and a varnished aluminium cap. Vials of the liquid fraction are closed with a chlorobutyl rubber stopper and a varnished aluminium cap.

Pack contains 1, 10, 25 or 100 vials of Vanguard DA_2Pi Lyophilisate fraction and 1, 10, 25 or 100 vials of 1 ml Vanguard CPV-L solvent fraction.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

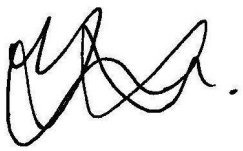
Vm 42058/4157

9. DATE OF FIRST AUTHORISATION

28 October 2005

10. DATE OF REVISION OF THE TEXT

March 2020



Approved: 06 March 2020