SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vanguard Lepto ci

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Quantity per 1 ml dose

Active substances:
Inactivated *Leptospira canicola*, between 420 and 740 RU*/dose.
Inactivated *Leptospira icterohaemorrhagiae*, between 463 to 915 RU*/dose.

* Relative units

For the full list of excipients see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.

Clear to slightly turbid, colourless liquid.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs from 7 weeks of age.

4.2 Indications for use, specifying the target species

Active immunisation of dogs to reduce clinical signs caused by *Leptospira canicola* and *Leptospira icterohaemorrhagiae*.

Onset of immunity occurs by approximately two weeks after the last dose of the Basic Vaccination Scheme.

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

None.

4.5 Special precautions for use

Special precautions for use in animals

Not applicable

Special precautions to be taken by the person administering the veterinary medicinal product to animals

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

4.6 Adverse reactions (frequency and seriousness)

On very rare occasions, vaccinated dogs may have a transient swelling (up to 3 cm) 4-6 hours after vaccination which resolves after approximately 7 days.

Very rarely, if a systemic anaphylactic reaction occurs (eg vomiting,) administer appropriate symptomatic treatment (e.g. adrenaline or an equivalent).

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, 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 are available which demonstrate that this vaccine can be mixed and administered with veterinary medicinal products from the Vanguard range containing canine distemper virus, canine parvovirus, canine adenovirus or canine parainfluenza virus or Vanguard R (where authorised) or administered on the same day at different injection sites.

After concurrent or mixed administration of Vanguard Lepto ci and Vanguard R, vaccinated dogs may have a transient swelling (up to 6 cm) and a transient swelling of the sub-mandibular and/or pre-scapular lymph nodes at the injection site 4 hours after vaccination which resolve within 24 hours

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except the products mentioned above. A decision to use this vaccine before or after any other veterinary medicinal product therefore 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.

Use with Vanguard R
To mix both products, one vial of Vanguard Lepto ci should be mixed with 1 ml of Vanguard R either in the Vanguard R vial or the syringe. Vanguard R will be well shaken before use. The mixed vaccines will be gently shaken and then administered immediately.

Basic Vaccination Scheme:
Puppies younger than 10 weeks of age
Two doses of Vanguard Lepto ci 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
Two doses of Vanguard Lepto ci at least 14 days apart.

Re-vaccination Scheme:
A single dose of Vanguard Lepto ci 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(s)

Not applicable.

5. IMMUNOLOGICAL PROPERTIES

The vaccine is intended for the active immunisation of healthy puppies and dogs against diseases caused by *Leptospira canicola* and *Leptospira icterohaemorrhagiae*.

ATC VET CODE : QI07AB01

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Phosphate buffered saline.

6.2 Incompatibilities

Do not mix with any other veterinary medicinal product other than those of the Vanguard range containing canine distemper virus, canine parvovirus, canine adenovirus or canine parainfluenza virus or Vanguard R (where authorised).

6.3 Shelf life

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), closed with a chlorobutyl rubber stopper and a varnished aluminium cap.

Each plastic pack contains 1, 10, 25 or 100 vials of 1 ml Vanguard Lepto ci.

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 42058/4161

9. DATE OF FIRST AUTHORISATION

25 October 2005

10. DATE OF REVISION OF THE TEXT

December 2023 Approved: 06 December 2023