

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Vanguard Lepto ci – 25 x 1 ml dose label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vanguard Lepto ci

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each vial contains inactivated *Leptospira canicola* (between 420 and 740 RU (Relative Units)) and *Leptospira icterohaemorrhagiae* (between 463 and 915 RU).

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

25 x 1 ml dose

5. TARGET SPECIES

Dogs from 7 weeks of age.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous injection.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated. Do not freeze.

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

Dispose of waste material in accordance with local requirements.

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.

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the 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 42058/5181

17. MANUFACTURER’S BATCH NUMBER

Batch {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial Label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vanguard Lepto ci

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Inactivated *Leptospira canicola* and *L. icterohaemorrhagiae* vaccine.

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

6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET
Vanguard Lepto ci

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 for the batch release:

Zoetis Belgium SA
rue Laid Burniat 1
1348 Louvain-la-Neuve
Belgium

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vanguard Lepto ci

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

A solution for injection, each 1 ml dose containing inactivated *Leptospira canicola* (between 420 and 740 RU (Relative Units)) and inactivated *Leptospira icterohaemorrhagiae* (between 463 and 915 RU).

4. INDICATION(S)

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

Onset of immunity occurs by approximately 2 weeks after the last dose of the Basic Vaccination Scheme.

The duration of immunity it is at least 12 months.

5. CONTRAINDICATIONS

Do not vaccinate unhealthy or pregnant animals.

6. ADVERSE REACTIONS

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 (eg 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 reaction(s) 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).>

If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs from 7 weeks of age.

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

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.

9. ADVICE ON CORRECT 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.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated (2°C-8°C). Do not freeze.

12. SPECIAL WARNING(S)

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.

Pregnancy:

Do not use during pregnancy.

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.

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

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).

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

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

The product is supplied in plastic packs of either 1, 10, 25 or 100 vials of 1 ml Vanguard Lepto ci. Not all pack sizes may be marketed.

Gavin Hall
Approved: 14 January 2025