ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vanguard Lepto-ci solution for injection for dogs

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

Excipients

Qualitative composition of excipients and other constituents
Sodium chloride
Anhydrous disodium phosphate
Monobasic potassium phosphate
Water for injections

3. CLINICAL INFORMATION

3.1 Target species

Dogs from 6 weeks of age.

3.2 Indications for use for each target species

For active immunisation of dogs to reduce infection caused by *Leptospira canicola* and *Leptospira icterohaemorrhagiae*.

Onset of immunity: approximately two weeks following the second vaccination.

Duration of immunity: twelve months have been demonstrated in studies performed on animals vaccinated at 8-9 weeks.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Not applicable.

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 and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Dogs:

Common (1 to 10 animals / 100 animals treated):	Injection site swelling[1]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Anaphylaxis[2]

[1] transient, for up to 7 days after vaccination
[2] If an anaphylactic reaction occurs e.g. vomiting, administer adrenaline or an equivalent

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:

Do not use during the whole of pregnancy.

3.8 Interaction with other medicinal products and other forms of interaction

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product. It is therefore recommended that no other vaccines should be administered within 14 days before or after vaccination with this product. A decision to use this vaccine more than 14 days before or after any other veterinary medicinal product needs to be made on a case by case basis.

3.9 Administration routes and dosage

Dosage and route of administration:
Shake well and immediately inject the entire contents of the vial (1 ml)subcutaneously.

Basic Vaccination Scheme:
The basic vaccination scheme requires two doses of the veterinary medicinal product to be administered to healthy animals from 6 weeks of age at least 14 days apart.

Re-vaccination Scheme:
Thereafter a single dose of the veterinary medicinal product 12 months after the Basic Vaccination Scheme is recommended on an annual basis to maintain the initialprotective effects of the vaccine induced by the Basic Vaccination Scheme

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

No adverse events other than those reported for a single dose administration were reported following administration of a double dose of the veterinary medicinal product.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI07AB01

To stimulate active immunity against *Leptospira canicola* and *Leptospira icterohaemorrhagiae* in healthy puppies and dogs.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 4 years
Shelf life after first opening the immediate packaging: use immediately.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

The vaccine is filled in 1 dose vials glass type I (Ph.Eur.).
Pack contains 1, 10, 25 or 100 vials of 1 ml.
Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Zoetis Belgium S.A.

7. MARKETING AUTHORISATION NUMBER(S)

VPA 10387/085/001

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 20/05/2004

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

10/2022

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).