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*, at least 40 hamster protective doses and inactivated *Leptospira icterohaemorrhagiae*, at least 40 hamster protective doses.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection.

4 CLINICAL PARTICULARS

4.1 Target Species

Canine from 6 weeks of age.

4.2 Indications for use, specifying the target species

For active immunisation of dogs to reduce infection caused by *Leptospira canicola* and *Leptospira icterohaemorrhagiae*. A twelve months duration of immunity has been demonstrated in studies performed on animals vaccinated at 8-9 weeks. The onset of immunity is approximately two weeks following the second vaccination.

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

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 attention showing a copy of the product literature.

4.6 Adverse reactions (frequency and seriousness)

Occasionally (approximately 10% of animals) administration of vaccine may be followed by a transient swelling at the site of injection for up to 7 days after vaccination. If an anaphylactic reaction occurs eg vomiting, administer adrenaline or an equivalent.

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

No information is available on the safety and efficacy from the concurrent use of this vaccine with any other. It is therefore recommended that no other vaccines should be administered within 14 days before or after vaccination with this product.

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.

Basic Vaccination Scheme:
The basic vaccination scheme requires two doses of Vanguard™ Lepto-ci to be administered to healthy animals from 6 weeks of age at least 14 days apart.

Re-vaccination Scheme:
Thereafter a single dose of Vanguard™ Lepto-ci 12 months after the Basic Vaccination Scheme is recommended on an annual basis to maintain the initial protective effects of the vaccine induced by the Basic Vaccination Scheme

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

No adverse events other than those reported for a single dose administration were reported following administration of an double dose of Vanguard™ Lepto-ci.

4.11 Withdrawal period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

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

Pharmacotherapeutic group: Inactivated Leptospira vaccine for dogs
ATCvet code: QI07AB01

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium chloride
Anhydrous disodium phosphate
Monobasic potassium phosphate
Water for injections

6.2 Incompatibilities

Do not mix with any other medicinal products.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 4 years.

6.4 Special precautions for storage

Store and transport refrigerated (+2°C to +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.). Pack contains 1, 10, 25 or 100 vials of 1 ml.
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, where appropriate

Any unused product or waste material should be disposed of in accordance with

national requirements.

7 MARKETING AUTHORISATION HOLDER

Zoetis Belgium S.A.
2nd Floor, Building 10
Cherrywood Business Park, Loughlinstown
Co Dublin
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA10387/085/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 20th May 2004
Date of last renewal: 19th May 2009

10 DATE OF REVISION OF THE TEXT

July 2017