IRISH MEDICINES BOARD ACT 1995

EUROPEAN COMMUNITIES (ANIMAL REMEDIES) (No. 2) REGULATIONS 2007

(S.I. No. 786 of 2007)

VPA:**10277/104/001**
Case No: 7003760

The Irish Medicines Board in exercise of the powers conferred on it by Animal Remedies (No. 2) Regulations (S.I. No. 786 of 2007) hereby grants to:

Schering Plough Limited

Shire Park, **Welwyn Garden City**, **Hertfordshire AL7 1TW**, **United Kingdom**

an authorisation, subject to the provisions of the said Regulations and the general conditions of the attached authorisation, in respect of the Veterinary Medicinal Product:

Procyon Dog Lepto

The particulars of which are set out in Part 1 and Part 2 of the said Schedule. The authorisation is also subject to any special conditions as may be specified in Part 2 of the said Schedule.

This authorisation,unless previously revoked, shall continue in force from **17/10/2008** to **16/10/2013**.

Signed on behalf of the Irish Medicines Board

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A person authorised in that behalf by the said Board.

Part II

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Procyon Dog Lepto
Suspension for injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Names of substances	Quantity per 1 ml dose
Active substances (inactivated)	
Leptospira interrogans serovar icterohaemorrhagiae (strain 115)	≥ 40 Hamster PD_{80} [1]
Leptospira interrogans serovar canicola (strain 117)	≥ 40 Hamster PD_{80}
Adjuvant	
Aluminium Hydroxide	1.63 -2.21 mg

[1] Hamster protective dose 80% (Ph. Eur.monograph)

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Suspension for injection.
Pink/red slightly opalescent suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

Dogs

4.2 Indications for use, specifying the target species

For the active immunisation of dogs from 6 weeks of age to prevent mortality and reduce clinical signs of disease caused by *Leptospira interrogans* serovars *canicola* and *icterohaemorrhagiae*.
Immunity has been demonstrated from 4 weeks after the primary vaccination course for *Leptospira interrogans* serovars *canicola* and *icterohaemorrhagiae*.
Duration of immunity by challenge is at least 12 months.

4.3 Contraindications

Do not use in dogs that have been treated with immuno-suppressive drugs or hyperimmune serum within the last month.

4.4 Special warnings for each target species

Following primary vaccination, dogs should remain isolated from possible sources of infection for at least 7 days to reduce risk of interference with the immune response.

4.5 Special precautions for use

Special precautions for use in animals
Avoid intradermal vaccination.

Special precautions to be taken by the person administering the medicinal product to animals
In the case of accidental self-injection or ingestion seek medical advice immediately and show the package insert or label to the physician.

4.6 Adverse reactions (frequency and seriousness)

A mild (<1cm^3), transient, local swelling may infrequently be seen at the injection site after the first intramuscular vaccination, which resolves completely without complication within a maximum of 3 weeks. Swelling commonly occurs at the injection site after the first or second subcutaneous vaccination; this swelling was up to 7.7 cm^3 (4 cm diameter) after the first vaccination and resolved within 2 weeks without complication. In rare cases the swelling may be severe.
In rare cases diarrhoea may be observed after vaccination and after intramuscular vaccination a single case (1%) of transient (1-2 day duration) lameness was observed.
Occasional hypersensitivity reactions may rarely occur. In such cases appropriate treatment, such as adrenaline or antihistamine, should be administered without delay.

4.7 Use during pregnancy, lactation or lay

No information is available on the use of the vaccine in pregnant bitches. Do not use in pregnant or lactating bitches.

4.8 Interaction with other medicinal products and other forms of interaction

No information is available on the compatibility of this vaccine with any other except Quantum Dog DA$_2$PPi.

Therefore the safety and efficacy of this product when used with any vaccine other than this (either when used on the same day or at different times) has not been demonstrated.

4.9 Amounts to be administered and administration route

The vaccine should be gently shaken and given by subcutaneous or intramuscular injection.

Primary vaccination:
Two doses of 1 ml given with an interval of 3-4 weeks.

Dogs and puppies 6 weeks of age and over:
Administer one dose by i.m or s.c injection, then a second dose 3 to 4 weeks later.

Booster vaccination:
Dose 1 ml

Booster vaccination is recommended at 12 month intervals to maintain immunity.

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

Dogs which receive an overdose of vaccine will exhibit similar adverse effects as described in section 4.6. Local swelling at the injection site (particularly when subcutaneous injection is used) may be larger (up to 10.7cm^3) and take longer to resolve (up to 33 days).

4.11 Withdrawal Period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

ATC Vet Code: QI07AB01
Pharmacotherapeutic Group: Immunologicals for canidae, inactivated leptospira vaccine.
To stimulate active immunity in dogs, the vaccine contains inactivated *Leptospira icterohaemorrhagiae* and *Leptospira canicola.*

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aluminium hydroxide
D-MEM (inorganic salts, amino acids, vitamins etc)

6.2 Incompatibilities

Do not mix with any other vaccine/immunological product.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 24 months

6.4 Special precautions for storage

Store and transport refrigerated between +2 °C and +8 °C. Protect from light. Do not freeze.

6.5 Nature and composition of immediate packaging

Clear glass vials, Type I (Ph. Eur.) nominal volume 4ml, containing 1 ml vaccine. Bromobutyl rubber closure sealed with orange-coded aluminium caps and polypropylene ‘flip-off’ covers.
Cardboard pack containing 10 vials
Cardboard pack containing 25 vials
Not all pack sizes may be marketed

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Any unused product or waste material should be disposed of by boiling, incineration or immersion in an appropriate disinfectant in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

Schering Plough Limited
Shire Park
Welwyn Garden City
Hertfordshire AL7 1TW
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10277/104/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

17th October 2008

10 DATE OF REVISION OF THE TEXT