IRISH MEDICINES BOARD ACT 1995

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

(S.I. No. 786 of 2007)

VPA: **10277/101/001**
Case No: 7004452

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 DA2PPi/L

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 the said Schedule.

The authorisation,unless revoked, shall continue in force from **31/03/2009** until **25/10/2012**.

Signed on behalf of the Irish Medicines Board

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A person authorised in that behalf by the said Board.

(NOTE: This authorisation replaces any previous authorisation in respect of this product which is now null and void.)

Part II

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Quantum Dog DA_2PPi/L	CMS except:
Procyon Dog DA_2PPi/L	UK and Ireland
Procyon DA_2PPi/L vet	Denmark, Finland, Norway, Sweden
Quantum Perro DA_2PPi/L	Spain
Quantum Cão DA_2PPi/L	Portugal
Quantum DA_2PPi/L für Hunde	Germany, Austria

Lyophilisate and solvent for suspension for injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

i. DA_2PPi – freeze dried fraction

Names of substances	Quantity per dose (log_{10} $TCID_{50}$[1])
Active substances (live attenuated)	
Canine distemper virus (Distemperoid strain)	4.5 – 6.0
Canine adenovirus-2 (Ditchfield strain)	3.9 - 6.0
Canine parvovirus (SAH 2b strain)	5.2 – 6.0
Canine parainfluenza virus (Philips Roxane strain)	4.8 – 7.0

ii. L – liquid diluent fraction

Names of substances	Quantity per 1 ml dose
Active substances (inactivated)	
Leptospira interrogans serovar *icterohaemorrhagiae* (strain 115)	≥ 40 Hamster PD_{80}[2]
Leptospira interrogans serovar *canicola* (strain 117)	≥ 40 Hamster PD_{80}[2]
Adjuvant	
Aluminium Hydroxide	1.63 -2.21 mg

[1] Tissue culture infective dose 50%

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

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for injection
The freeze dried fraction is a lightish brown pellet and the solvent (and the reconstituted product) is a 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 canine distemper virus, canine parvovirus and infectious canine hepatitis
- to prevent mortality and reduce clinical signs of disease caused by *Leptospira interrogans* serovars *canicola* and *icterohaemorrhagiae*
- to reduce clinical signs and viral shedding of canine adenovirus type 2
- to reduce viral shedding of canine parainfluenza virus and canine parvovirus

Immunity has been demonstrated from:
- 3 weeks after the first dose for parvovirus,
- 3 weeks after the primary vaccination course for distemper
- 4 weeks after the primary vaccination course for canine adenovirus and *Leptospira interrogans* serovars *canicola* and *icterohaemorrhagiae*
- 3 weeks after the primary vaccination course (serological response only) for parainfluenza

Duration of immunity is 4 years for distemper, adenovirus (CAV1 and CAV2) and parvovirus and 12 months by challenge for parainfluenza and *Leptospira interrogans* serovars *canicola* and *icterohaemorrhagiae*

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.
The presence of maternally derived antibodies (MDA) in young puppies may interfere with the development of a protective immune response following vaccination. Nevertheless, the vaccine has been demonstrated to be efficacious in puppies with moderate levels of MDA to canine distemper virus (CDV), canine parvovirus (CPV), and canine adenovirus (CAV). Intramuscular vaccination gives a slightly higher serological response than subcutaneous vaccination. Thus, if particularly high and persistent levels of MDA against CPV or CDV are suspected or measured (e.g. for CDV >30 units SN at first vaccination) then intramuscular vaccination is recommended and the first vaccination should be delayed to 8 weeks of age.
Following vaccination, the vaccine viruses CAV-2 and CPV will be excreted and can spread to unvaccinated animals in contact but will not cause disease. Canine parainfluenza (CPi) may also be excreted but will not spread.
Cats (a non-target species) are known to be susceptible to CPV, and therefore in contact animals may develop antibodies but not disease.

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. Pregnant bitches should not come into contact with recently vaccinated animals.

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 the product.

4.9 Amounts to be administered and administration route

Each dose is prepared by reconstituting a vial of freeze dried (DA_2PPi) fraction with a vial of liquid (L) fraction. The reconstituted vaccine should be gently shaken and given immediately 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, but not before 10 weeks of age.

Booster vaccination:
Dose 1 ml:
In order to maintain immunity against CPi, *L. icterohaemorrhagiae* and *L. canicola*, annual revaccination is required against these components. To maintain immunity against CPV, CDV and CAV revaccination at intervals of up to 4 years is required.

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

ATCvet code: QI07AI02
To stimulate active immunity in dogs, the vaccine contains live canine distemper virus, canine adenovirus, canine parvovirus (strain 2b) and canine parainfluenza virus plus inactivated *Leptospira icterohaemorrhagiae* and *Leptospira canicola.* Challenge studies against canine parvovirus were conducted with the 2b strain only.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aluminium hydroxide
Sucrose
Gelatin
Casein hydrolysate
D-MEM (inorganic salts, vitamins, amino acids etc*)*

6.2 Incompatibilities

Do not mix with any other vaccine/immunological product

6.3 Shelf-life

As packaged for sale - 18 months
Use the vaccine immediately after reconstitution.

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 4 ml, containing 1 ml L fraction or a freeze-dried vaccine plug of DA_2PPi fraction.. Bromobutyl rubber closure sealed with colour-coded aluminium caps and polypropylene ‘flip-off’ covers.
Cardboard pack containing 10 vials of DA_2PPi and 10 of L
Cardboard pack containing 25 vials of DA_2PPi and 25 of L

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 10277/101/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

26th October 2007

10 DATE OF REVISION OF THE TEXT

31st March 2009