

IRISH MEDICINES BOARD ACT 1995

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

(S.I. No. 786 of 2007)

VPA: **10277/090/001**
Case No: 7005764

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/CvL

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 previously revoked, shall continue in force from **13/11/2009**.

Signed on behalf of the Irish Medicines Board

A person authorised in that behalf by the said Board.

(NOTE: From this date of effect, 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

Procyon Dog DA₂PPi/CvL

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

i DA₂PPi – freeze dried fraction

Quantity per dose
(log₁₀ TCID₅₀¹)

<u>Active substances (live attenuated)</u>	
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. CvL – liquid diluent fraction

Quantity per 1 ml dose

<u>Active substances (inactivated)</u>	
Feline corona virus (strain FEC-SAH)	≥ 6.3 log ₂ SN units ²
<i>Leptospira interrogans</i> serovar <i>icterohaemorrhagiae</i> (strain 115)	≥ 40 Hamster PD ₈₀ ³
<i>Leptospira interrogans</i> serovar <i>canicola</i> (strain 117)	≥ 40 Hamster PD ₈₀ ³
<u>Adjuvant</u>	
Aluminium Hydroxide	1.63 -2.21 mg

¹ Tissue culture infective dose 50%
² Serum Neutralisation value in guinea pig potency test
³ Hamster protective dose 80% (Ph. Eur.monograph)

Excipients:

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for injection

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
- to reduce intestinal infection caused by canine coronavirus

Immunity has been demonstrated from:

- 3 weeks after the first dose for parvovirus,
- 3 weeks after the primary vaccination course for distemper and coronavirus
- 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 for parainfluenza, coronavirus 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

Dogs should not be exposed to unnecessary risk of infection within the first week after vaccination. 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.

Some puppies may be seropositive to coronavirus (due to field exposure or MDA) at the minimum age of 6 weeks. No additional benefit may be derived from vaccinating seropositive animals.

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

Only healthy dogs should be vaccinated
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 ($<1\text{ cm}^3$), 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 $<8\text{ cm}^3$ (4 cm diameter) after the first vaccination and resolved within 2 weeks without complication. In rare cases, swellings may be painful. In very rare cases, a transient rise in body temperature, lethargy, anorexia or diarrhoea may be observed after vaccination. Transient lameness (1-2 day duration) may occur after intramuscular vaccination. 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

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 of this vaccine when used with any other veterinary medicinal product. 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.

4.9 Amounts to be administered and administration route

Each dose is prepared by reconstituting a vial of freeze dried (DA₂PPi) fraction with a vial of liquid (CvL) 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.

Administer one dose by i.m or s.c injection to dogs from 6 weeks of age and over, 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, canine coronavirus, *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 $<11\text{ cm}^3$) and take longer to resolve (up to 33 days).

4.11 Withdrawal Period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

ATCvet code: QI07AJ10

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 coronavirus, *Leptospira icterohaemorrhagiae* and *Leptospira canicola*. Challenge studies against canine parvovirus were conducted with the 2b strain. The pathogenic role of canine coronavirus is poorly understood. Experimental challenge did not cause clinical disease to the unvaccinated dogs, but vaccination did reduce intestinal infection.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

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

6.2 Incompatibilities

Do not mix with any other medicinal 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 (2 °C - 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 CvL fraction or a freeze-dried vaccine plug of DA₂PPi fraction. Bromobutyl rubber closure sealed with colour-coded aluminium caps and polypropylene ‘flip-off’ covers.

Cardboard pack containing 10 vials of DA₂PPi and 10 of CvL

Cardboard pack containing 25 vials of DA₂PPi and 25 of CvL

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 Ltd,
Shire Park
Welwyn Garden City
Herts
AL7 1TW
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10277/090/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

13th November 2009

10 DATE OF REVISION OF THE TEXT