IRISH MEDICINES BOARD ACT 1995

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

(S.I. No. 786 of 2007)

VPA:**10277/105/001**
Case No: 7004027

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 Parvo Lyophilisate and solvent for suspension for injection.

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 **06/02/2009** to **05/02/2014**.

Signed on behalf of the Irish Medicines Board

_____

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 Parvo
Lyophilisate and solvent for suspension for injection.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

i. P - freeze dried fraction

Names of substances	Quantity per dose (log_{10} $TCID_{50}$[1])
Active substance (live attenuated)	
Canine parvovirus (SAH 2b strain)	5.2 – 6.0

ii. Liquid diluent fraction

Names of substances	Quantity per 1 ml dose
Adjuvant	
Aluminium Hydroxide	1.63 -2.21 mg

[1] Tissue culture infective dose 50%

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

Dog

4.2 Indications for use, specifying the target species

For the active immunisation of dogs from 6 weeks of age to reduce viral shedding, prevent mortality, and reduce clinical signs of disease caused by canine parvovirus strain 2b. Immunity has been demonstrated from 3 weeks after the first vaccination.
Duration of immunity is 4 years.

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

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 parvovirus (CPV). Intramuscular vaccination gives a slightly higher serological response than subcutaneous vaccination. Thus, if particularly high and persistent levels of MDA against CPV are suspected or measured, then intramuscular vaccination is recommended and the first vaccination should be delayed to 8 weeks of age.
Dogs should not be exposed to unnecessary risk of infection within the first week after vaccination.
Following vaccination, the vaccine virus CPV will be excreted and can spread to unvaccinated animals in contact but will not cause disease.
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 veterinary medicinal product to animals
In the case of accidental self-injection or ingestion seek medical advice immediately and show the package leaflet 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 <8 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. 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

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

4.9 Amounts to be administered and administration route

Each dose is prepared by reconstituting a vial of freeze dried vaccine with a vial of diluent. 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:
To maintain immunity against CPV, 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 (<11 cm^3) and take longer to resolve (up to 33 days).

4.11 Withdrawal Period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

QI07AD01
To stimulate active immunity in dogs, the vaccine contains live canine parvovirus (strain 2b). 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

Lyophilisate: 2 years
Diluent: 1 year
As packaged for sale: 1 year
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 diluent or a freeze-dried vaccine plug of Parvo fraction.. Bromobutyl rubber closure sealed with colour-coded aluminium caps and polypropylene ‘flip-off’ covers.
Cardboard pack containing 10 vials of Parvo and 10 of diluent
Cardboard pack containing 25 vials of Parvo and 25 of diluent

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 10277/105/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

6th February 2009

10 DATE OF REVISION OF THE TEXT