Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Procyon Dog Pi/CvL

Lyophilisate and solvent for suspension for injection for dogs.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

i. Pi – freeze dried fraction

Active substance (live attenuated)	Quantity per dose (log_{10} $TCID_{50}$[1])
Canine parainfluenza virus (Philips Roxane strain)	4.8 – 6.1

ii. CvL – liquid diluent fraction

Active substances (inactivated)	Quantity per 1 ml dose
Feline coronavirus (strain FEC-SAH)	$\geq$ 6.3 log_2 SN units[2]
Leptospira interrogans serovar *icterohaemorrhagiae* (strain 115)	$\geq$ 40 Hamster PD_{80}[3]
Leptospira interrogans serovar *canicola* (strain 117)	$\geq$ 40 Hamster PD_{80}[3]
Adjuvant	
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 *Leptospira interrogans* serovars *canicola* and *icterohaemorrhagiae*;
- to reduce viral shedding of canine parainfluenza virus
- to reduce intestinal infection caused by canine coronavirus

Immunity has been demonstrated from:

- 3 weeks after the primary vaccination course for parainfluenza (serological response only) and for coronavirus
- 4 weeks after the primary vaccination course for *Leptospira interrogans* serovars *canicola* and *icterohaemorrhagiae*

Duration of immunity by challenge is 12 months.

4.3 Contraindications

Do not use in dogs that have been treated with immunosuppressive drugs or hyper-immune serum within the last month.

4.4 Special warnings for each target species

Dogs should not be exposed to unnecessary risk of infection during 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. Intramuscular vaccination gives a slightly higher serological response. Thus, if particularly high levels of MDA are suspected or measured, then intramuscular vaccination is recommended and/or vaccination should be delayed appropriately.
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, canine parainfluenza virus may be excreted but will not spread.

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 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 (<1 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 up to 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 days 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 the freeze dried (Pi) fraction with a vial of the 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:
Booster vaccination is recommended annually to maintain immunity to the constituent components.

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

Dogs which receive an overdose of vaccine will exhibit similar adverse effects as described for a single dose. Local swelling at the injection site (particularly when subcutaneous injection is used) may be larger (up to 11 cm^3) and take longer to resolve (up to 33 days).

4.11 Withdrawal Period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Live canine parainfluenza virus + inactivated Leptospira + inactivated canine coronavirus

ATC vet code: QI07AJ12

To stimulate active immunity in dogs, the vaccine contains live canine parainfluenza virus plus inactivated coronavirus, *Leptospira icterohaemorrhagiae* and *Leptospira canicola.* 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 veterinary medicinal product, except the solvent supplied for use with the product.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 15 months
Shelf life after reconstitution according to directions: Use immediately.

6.4 Special precautions for storage

Store and transport refrigerated (2 °C – 8 °C).
Do not freeze.
Protect from light.

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 Pi fraction.
Bromobutyl rubber closure sealed with colour-coded aluminium caps and polypropylene ‘flip-off’ covers.

Cardboard pack containing 10 vials of Pi fraction and 10 vials of CvL fraction
Cardboard pack containing 25 vials of Pi fraction and 25 vials of CvL fraction
Not all pack sizes may be marketed.

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

Dispose of waste material by boiling, incineration or immersion in an appropriate disinfectant approved for use by the competent authorities.

7 MARKETING AUTHORISATION HOLDER

Intervet Ireland Ltd.
Magna Drive
Magna Business Park
Citywest Road
Dublin 24

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10996/217/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

13th September 2010

10 DATE OF REVISION OF THE TEXT

January 2011