Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Duramune Pi + LC

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Qualitive composition:

Combined canine parainfluenza virus vaccine (live), lyophilisate, canine leptospirosis vaccine (inactivated) and canine coronavirus vaccine (inactivated).

Quantitative composition:

1. Lyophilisate fraction:

Active Substances	**Per 1ml dose**
canine Parainfluenza virus, Strain FDL	$10^{5.1}$ to $10^{7.4}$ $TCID_{50}$*

*$TCID_{50}$ = tissue culture 50% infective dose

Excipients

For a full list of excipients, see section 6.1

2. Liquid solvent fraction:

Active Substances	**Per 1 ml dose**
Inactivated *Leptospira interrogans* bacteria (outer membrane coat)	
Serogroup *canicola*, serovar *canicola*	Potency according to Ph. Eur.*
Serogroup *icterohaemorrhagiae*, serovar *icterohaemorrhagiae*	Potency according to Ph. Eur.*
Canine coronavirus, strain TN449 (inactivated)	RP**1.0 - 2.0
Adjuvants	
Ethylene/Maleic anhydride (EMA-31)	0.01ml
Neocryl	0.03ml

Excipients

For a full list of excipients, see section 6.1

* hamster 80% protective dose according to Ph. Eur.

** RP = Relative Potency

3 PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for injection.

Lyophilisate: Cream-yellow colour powder
Solvent: Opaque White liquid
Reconstituted vaccine: orange or yellowish colour with light opalescence.

4 CLINICAL PARTICULARS

4.1 Target Species

Dogs.

4.2 Indications for use, specifying the target species

For the active immunisation of dogs to reduce clinical signs due to infection with canine parainfluenza virus and reduce shedding of canine parainfluenza virus; to prevent mortality and reduce clinical signs due to *Leptospira interrogans*, serovars *canicola* and *icterohaemorrhagiae*; and to reduce infection at the intestinal level caused by canine coronavirus.
The onset of immunity is from two weeks after the second vaccination. The duration of immunity is one year; after one year only a reduction of oculo-nasal discharge has been demonstrated following a canine parainfluenza challenge.

4.3 Contraindications

See section 4.7.

4.4 Special warnings for each target species

The canine parainfluenza virus strain, strain FDL, present in the vaccine may spread to unvaccinated animals, but does not cause disease.
Animals that have received immunosuppressive drugs (e.g. glucocorticoids) should not be vaccinated until an interval of at least 4 weeks has elapsed.

4.5 Special precautions for use

Special precautions for use in animals

None.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

In the case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

4.6 Adverse reactions (frequency and seriousness)

Following the first vaccination, it is very common for puppies to develop a small visible swelling (<2 cm) lasting for generally only two days. Following the second vaccination, it is common for a small visible swelling (up to 5 cm) to be seen at the injection site, which may last for up to five days. The swelling may be painful for 1 to 2 days.
In most cases, these small and transient injection site reactions resolve with no need for treatment.
In very rare cases, type I hypersensitivity reactions (facial oedema, urticaria, anaphylactic reaction), vomiting and diarrhoea may be observed after vaccination. In the event of an allergic or anaphylactic reaction, immediate appropriate symptomatic treatment should be given.

4.7 Use during pregnancy, lactation or lay

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 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.

See section 4.4.

4.9 Amounts to be administered and administration route

The vaccine is to be administered subcutaneously to dogs of the age of 6 weeks and older.
Aseptically reconstitute the contents of the lyophilisate vial using the liquid vaccine. Shake well before use. The entire contents of the reconstituted vial should be administered as a single dose. Syringes and needles should not have been sterilised chemically or be above ambient temperature. Do not use chemicals to disinfect or sterilise skin.

Puppies 6-10 weeks of age
The initial vaccination course consists of two vaccinations. The first vaccination should be given between 6-8 weeks of age and the second vaccination should be given from 10 weeks of age.

Puppies of at least 10 weeks of age
Two vaccinations should be given with an interval of 2-4 weeks between doses.

Booster vaccination
An annual booster vaccination with one dose of Duramune Pi + LC is recommended.

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

Some puppies may exhibit a transient lethargy by 4 hours post vaccination but recover by two days post vaccination. Occasionally a small visible swelling (< 5 cm) may be seen at the injection site, which may last for up to 17 days. Transient mild hyperthermia lasting not more than 24 hours may very commonly be seen in dogs given an overdose.

4.11 Withdrawal Period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

To stimulate active immunity against canine parainfluenza virus, *Leptospira interrogans* serogroup canicola, *Leptospira interrogans* serogroup icterohaemorrhagiae and canine coronavirus.

ATCVet Code: QI07AJ12.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

1. Lyophilisate fraction:
Sucrose
Gelatin
Bactopeptone
Potassium phosphate dibasic
Potassium phosphate monobasic
Sodium hydroxide
Eagle's Earle's medium with HEPES

2. Liquid solvent fraction:
Ethylene/Maleic anhydride (EMA-31)
Neocryl
Sodium chloride
Sodium phosphate dibasic
Potassium phosphate monobasic
Water for injections

6.2 Incompatibilities

Do not mix with any other veterinary medicinal product, except the solvent vaccine supplied for use with the product.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after reconstitution according to directions: Use immediately.

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

Lyophilisate Fraction
Vial: Type I (Ph.Eur.) glass.
Closure: Bromobutyl rubber stoppers sealed with aluminium caps.

Liquid solvent Fraction
Vial: Type I (Ph.Eur.) glass.
Closure: Chlorobutyl rubber stoppers sealed with aluminium caps.

Pack Sizes
Packs with 10, 25, 50 or 100 x 1 ml doses. Each dose is a combination of one vial of lyophilisate vaccine and one vial of liquid vaccine.

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

Zoetis Ireland Limited
25/28 North Wall Quay
Dublin 1
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA: 10438/042/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 22nd November 2006

Date of last renewal: 21st November 2011

10 DATE OF REVISION OF THE TEXT

January 2014