

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Duramune Puppy DP + C

Lyophilisate and solvent for suspension for injection for dogs

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1. Lyophilisate fraction:

<u>Active Ingredients</u>	<u>Per 1 ml dose</u>
Canine Distemper virus, strain Onderstepoort	$\geq 10^{2.5}$ to $\leq 10^{4.8}$ TCID ₅₀ *
Canine Parvovirus, strain SAH	$\geq 10^{4.7}$ to $\leq 10^{6.5}$ TCID ₅₀ *

*TCID₅₀ = tissue culture 50% infective dose

2. Liquid solvent fraction:

<u>Active Ingredients</u>	<u>Per 1 ml dose</u>
Canine Coronavirus, strain TN449	RP* 1.0-2.0
<u>Adjuvant</u>	
Ethylene/Maleic anhydride (EMA-31)	0.01 ml
Neocryl	0.03 ml

*RP = Relative Potency

Excipients:

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for injection.

Lyophilisate: Cream-yellow colour powder

Solvent: opaque liquid.

4 CLINICAL PARTICULARS

4.1 Target Species

Dogs.

4.2 Indications for use, specifying the target species

For the active immunisation of dogs to prevent mortality and reduce disease caused by canine distemper virus; to prevent mortality and disease and reduce virus shedding caused by canine parvovirus infection; 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 at least three years for canine distemper and at least 1 year for canine corona virus.

The duration of immunity for the canine parvovirus component has been demonstrated to be at least three years following challenge with CPV2b. A duration of immunity of at least 1 year has been proven after CPV2a challenge. Duration of immunity against CPV2c has not been investigated. Demonstration of onset of immunity against canine parvovirus was conducted by challenge studies using virulent CPV2a and CPV2b following vaccination from 6 weeks of age and CPV2c following vaccination from 8 weeks of age.

4.3 Contraindications

Only vaccinate healthy dogs.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

The efficacy of the CDV and CPV components of the vaccine may be reduced due to maternal antibody interference. However, the vaccine has been proven to be of benefit in the presence of maternal antibody levels that are likely to be encountered under field conditions against virulent challenge by CDV and CPV (2a and 2b). Efficacy against CPV-2c in the presence of MDA has not been investigated. In situations where higher MDA levels are expected the vaccination protocol should be planned accordingly.

The live vaccine strains may spread to unvaccinated animals, but do 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.

The vaccine may not be effective in dogs incubating the disease at the time of vaccination.

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

In 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, small it is very common to see a visible swelling (up to 5 cm) 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 any animal population there will be a small number of individuals, which fail to respond fully to vaccination.

In very rare cases hypersensitivity reactions such as facial oedema may occur. In these cases a symptomatic therapy is recommended.

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 decided on a case by case basis.

4.9 Amounts to be administered and administration route

Vaccination Schedule

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.

Primary vaccination:

Pups 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.

Pups of at least 10 weeks of age

Two vaccinations should be given with an interval of 2-4 weeks between doses.

Booster vaccination

Administer a single dose by subcutaneous injection one year after completion of the primary vaccination schedule. Subsequent booster vaccinations should be administered at intervals of not less than one year and not more than three years. If intervals longer than one year are implemented, immunity against canine coronavirus should be assured by administering a suitable canine coronavirus vaccine at intervals of not more than one year. For booster vaccinations against CPV the epidemiological situation should be taken into consideration.

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 is very common in dogs given an overdose.

4.11 Withdrawal Period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

To stimulate active immunity against canine distemper virus, canine parvovirus and canine coronavirus.

ATC Code: QI07AH04

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lyophilisate fraction:

Sucrose
Gelatin
Bactopeptone
Potassium Phosphate Dibasic
Potassium Phosphate Monobasic
Sodium Hydroxide
Eagle's Earle's with HEPES

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 supplied for use with the product.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 18 months.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Pfizer Animal Health
Ringaskiddy
Co. Cork
Ireland.

8 MARKETING AUTHORISATION NUMBER(S)

VPA: 10019/168/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

29th June 2010

10 DATE OF REVISION OF THE TEXT

November 2013