

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Duramune DAPPi + L
Lyophilisate and solvent for suspension for injection for dogs

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1. Lyophilisate:

Active Ingredients

Canine distemper virus, strain Onderstepoort

Canine adenovirus type 2, strain V197

Canine parainfluenza virus, Strain FDL

Canine parvovirus, strain SAH

*TCID₅₀ = tissue culture 50% infective dose

Excipients

For a full list of excipients, see section 6.1.

2. Solvent:

Active Ingredients

Inactivated *Leptospira interrogans* bacteria (outer membrane coat)

Serogroup *canicola*, Serovar *canicola*

Serogroup *icterohaemorrhagiae*, serovar *icterohaemorrhagiae*

Ajuvant

Ethylene/Maleic anhydride (EMA)

Neocryl A640

Exipients

For a full list of excipients, see section 6.1.

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

Per 1 ml dose

10^{2.5} to 10^{4.8} TCID₅₀ *

10^{4.8} to 10^{7.0} TCID₅₀

10^{5.1} to 10^{7.4} TCID₅₀

10^{4.7} to 10^{6.5} TCID₅₀

Per 1 ml dose

Potency according to
Ph.Eur. *

Potency according to
Ph.Eur. *

0.01ml

0.03 ml

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 disease caused by canine distemper virus; to prevent mortality and disease and reduce virus shedding caused by canine parvovirus infection; to prevent mortality and reduce clinical signs caused by infectious canine hepatitis and *Leptospira interrogans* serovars *icterohaemorrhagiae* and *canicola*; and to reduce clinical signs and infection caused by canine adenovirus 2 and to reduce clinical signs and shedding caused by infection with canine parainfluenza virus.

The onset of immunity is from two weeks after the second vaccination.

The duration of immunity is at least three years for the canine distemper and canine adenovirus components and at least one year for all other antigens.

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.

After one year only a reduction of oculo-nasal discharge has been demonstrated following canine parainfluenza challenge.

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, CPV and CAV 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, CAV 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.

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, it is very common to see a small visible swelling (occasionally 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 very rare cases, type I hypersensitivity (facial oedema, urticaria, anaphylactic reaction), vomiting, diarrhoea and lethargy may be observed after vaccination. In the event of an allergic or anaphylactic reaction, immediate appropriate symptomatic treatment should be given.

In any animal population there will be a small number of individuals, which fail to respond fully to vaccination.

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.

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 lyophilisate with the solvent provided. Shake well before use. The entire contents of the reconstituted vial should be administered as a single dose.

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 the canine parainfluenza virus and leptospiral antigens should be assured by administering a suitable combined canine parainfluenza, *L. icterohaemorrhagiae*, and *L. canicola* 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 adenovirus, infectious canine hepatitis, canine parainfluenza virus, canine parvovirus, *Leptospira interrogans* serogroup canicola and *Leptospira interrogans* serogroup icterohaemorrhagiae.

ATCVet code: QI07AI02

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

1. Lyophilisate:

Sucrose

Gelatin

Bactopeptone

Dipotassium phosphate

Potassium dihydrogen phosphate

Potassium hydroxide

Eagle's Earle's medium with HEPES

May contain HCl or NaOH for pH correction

2. Solvent:

Ethylene/Maleic anhydride (EMA)

Neocryl A640

Sodium chloride

Disodium phosphate

Potassium dihydrogen phosphate

Water for injections

May contain HCl or NaOH for pH correction

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).

Protect from light.

Do not freeze.

6.5 Nature and composition of immediate packaging

Lyophilisate

Vial: Type I (Ph.Eur.) glass. 3 ml capacity

Closure: Type I (Ph.Eur.) grey or red bromobutyl rubber stoppers sealed with aluminium crimp caps

Solvent

Vial: High-density polypropylene.

Closure: Chlorobutyl snap-on rubber stoppers with centre hole caps sealed with aluminium crimp 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 solvent.

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

Pfizer Animal Health
Ringaskiddy
Co. Cork
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10019/165/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

7th October 2011

10 DATE OF REVISION OF THE TEXT

August 2013