1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CANIXIN DHPPi/L lyophilisate and suspension for suspension for injection for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 1 ml contains:

Active substances:

Lyophilisate

Live attenuated canine distemper virus (CDV) - Lederle strain	$10^{3.0}$ - $10^{4.9}$ $CCID_{50}$*
Live attenuated canine adenovirus type 2 (CAV-2) - Manhattan strain	$10^{4.0}$ - $10^{6.0}$ $CCID_{50}$*
Live attenuated canine parvovirus (CPV) - CPV780916 strain	$10^{5.0}$ - $10^{6.8}$ $CCID_{50}$*
Live attenuated canine parainfluenza virus (CPiV) - Manhattan strain	$10^{5.0}$ - $10^{6.9}$ $CCID_{50}$*

* Cell culture infectious dose 50%

Suspension

Inactivated *Leptospira interrogans*:	
- serogroup Canicola serovar Canicola, strain 601903	4350 - 7330 U**
- serogroup Icterohaemorrhagiae serovar Icterohaemorrhagiae, strain 601895	4250 - 6910 U**

** Antigenic mass ELISA units

Excipients:

Qualitative composition of excipients and other constituents
Lyophilisate :
Gelatin
Potassium hydroxide
Lactose monohydrate
Glutamic acid
Potassium dihydrogen phosphate
Dipotassium phosphate
Water for injections
Sodium chloride
Disodium phosphate
Suspension :
Sodium hydroxide (for pH adjustment)

Sucrose
Dipotassium phosphate
Potassium dihydrogen phosphate
Tryptone
Water for injections

Lyophilisate: White lyophilisate
Suspension: Translucent liquid

3. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each target species

For active immunisation of dogs from 8 weeks of age to:

- prevent mortality and clinical signs caused by CDV;
- prevent mortality and clinical signs caused by canine adenovirus type 1 (CAV-1);
- prevent clinical signs and mortality and reduce excretion caused by CPV in challenge studies performed with a CPV-2b strain;
- prevent clinical signs and reduce excretion caused by CPV in a challenge study performed with a CPV-2c strain;
- reduce respiratory clinical signs and viral excretion caused by CPiV and CAV-2;
- prevent mortality and reduce infection, clinical signs, kidney colonisation, renal lesions and urine shedding of *L.*Canicola;
- reduce infection, clinical signs, kidney colonisation and urine shedding of *L.* Icterohaemorrhagiae;

Onset of immunity:
The onset of immunity has been demonstrated from 3 weeks after the primary vaccination for CDV, CAV-2 and CPV, 4 weeks for CAV-1 and CPiV, 5 weeks for *L.* Canicola and 2 weeks for *L.* Icterohaemorrhagiae.

Duration of immunity:
After the primary vaccination course, the duration of immunity lasts for one year for all components.
In the duration of immunity studies one year after the basic vaccination scheme there was no significant difference between vaccinated and control dogs in viral excretion for CPiV and CAV-2, in reduction of kidney colonisation for *L.* Canicola and *L.* Icterohaemorrhagiae, nor in renal lesions and urine shedding for *L.* Canicola.
After the annual booster, the duration of immunity lasts for 3 years for CDV, CAV-1, CAV-2 and CPV.
For CAV-2, the duration of immunity after the annual booster was not established by challenge, and is based on the presence of CAV-2 antibodies 3 years after the booster vaccination.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

The presence of maternally derived antibodies (puppies from vaccinated females) may in some cases interfere with the vaccination. Therefore the vaccination scheme should be adapted accordingly (see section 3.9).

3.5 Special precautions for use

Special precautions for safe use in the target species:

After vaccination the live viral vaccinal strains (CAV-2, CPV) can be spread to unvaccinated animals without any pathological effect for these in-contact animals.

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.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Dogs:

Common (1 to 10 animals / 100 animals treated):	Injection site swelling[1,2,3], Injection site oedema[2,3,4] Lethargy[2]
Rare (1 to 10 animals / 10,000 animals treated):	Injection site pain[2,3], Injection site pruritus[2,3] Hyperthermia[2], Anorexia[2] Digestive tract disorders[2] (e.g. Diarrhoea[2], Vomiting[2])
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersensitivity reaction (e.g. Anaphylaxis, Allergic skin reaction such as Allergic oedema, Urticarial erythema, Allergic pruritus)[5]

[1] (≤ 4 cm)
[2] Transient

[3] Resolves spontaneously within 1 to 2 weeks.
[4] Slight diffuse
[5] Appropriate symptomatic treatment should be administered without delay.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
Do not use during pregnancy and lactation.

3.8 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.

3.9 Administration routes and dosage

After reconstitution of the lyophilisate with the solvent, shake gently and administer immediately one dose of 1 ml subcutaneously according to the following vaccination schedule:

Primary vaccination course:
- first injection from 8 weeks of age
- second injection 3 or 4 weeks later.

Maternally derived antibodies may in some cases influence the immune response to vaccination. In such cases, a third injection is recommended from 15 weeks of age.

Re-vaccinations:
One booster injection of a single dose should be given one year after the primary vaccination course.
Subsequent vaccinations are carried out at intervals of up to three years.
Annual revaccination is required for CPiV and Leptospira components, therefore a single dose of the Virbac vaccine against CPiV and Leptospira can be used annually.

The appearance of the reconstituted product is slightly pinkish beige.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

The administration of a 10 fold overdose at a single injection site did not cause any reactions other than those mentioned in the section 3.6 ‘Adverse events’ except that the duration of local reactions was increased (up to 26 days).

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit

the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI07AI02

To stimulate active immunity against canine distemper virus, canine adenovirus, canine parvovirus, canine parainfluenza virus and *L. interrogans* serogroup Canicola and *L. interrogans* serogroup Icterohaemorrhagiae.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 18 months.
Shelf life after reconstitution according to directions: use immediately.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

Colourless type I glass vial containing 1 dose of lyophilisate and colourless type I glass vial containing 1 ml of suspension, both closed by a butyl-elastomer stopper and sealed with an aluminium cap, in a plastic or cardboard box.

Pack sizes:
1 x 1 dose lyophilisate and 1 x 1 mL suspension
10 x 1 dose lyophilisate and 10 x 1 mL suspension
25 x 1 dose lyophilisate and 25 x 1 mL suspension
50 x 1 dose lyophilisate and 50 x 1 mL suspension
100 x 1 dose lyophilisate and 100 x 1 mL suspension

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

VIRBAC

7. MARKETING AUTHORISATION NUMBER(S)

VPA10988/101/002

8. DATE OF FIRST AUTHORISATION

11/12/2015

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

14/12/2023

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).