SUMMARY OF PRODUCT CHARACTERISTICS

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

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Lyophilisate and suspension for suspension for injection.
Lyophilisate: White lyophilisate
Suspension: Translucent liquid

4. CLINICAL PARTICULARS

4.1 Target species

Dog.

4.2 Indications for use, specifying the target species

For active immunisation of dogs from 8 weeks of age to:
- prevent mortality and clinical signs caused by canine distemper virus;
- prevent mortality and clinical signs caused by canine adenovirus type 1;
- prevent clinical signs and mortality and reduce excretion caused by canine parvovirus in challenge studies performed with a CPV-2b strain;
- prevent clinical signs and reduce excretion caused by canine parvovirus in a challenge study performed with a CPV-2c strain;
- reduce respiratory clinical signs and viral excretion caused by canine parainfluenza virus and canine adenovirus type 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.

4.3 Contraindications

None.

4.4 Special warnings for each target species

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 4.9).

4.5 Special precautions for use

Special precautions for use in animals

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.

4.6 Adverse reactions (frequency and seriousness)

A transient swelling (≤ 4 cm) or slight diffuse local oedema in rare cases associated with pain or pruritus was commonly observed in safety studies. Any such local reaction resolves spontaneously within 1 to 2 weeks.

Some transient post-vaccinal lethargic states were commonly observed in clinical studies.
Transient hyperthermia or digestive disturbances such as anorexia, diarrhoea or vomiting were rarely observed from spontaneous reports.

Hypersensitivity reactions (e.g. anaphylaxis, skin manifestations such as oedema/swelling, erythema, pruritus) have been reported in very rare cases from spontaneous reports. In case of such an allergic or anaphylactic reaction, appropriate symptomatic treatment should be administered.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s)
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports)

4.7 Use during pregnancy, lactation or lay

Do not use during pregnancy and lactation.

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

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 Canine Parainfluenza virus and Leptospira can be used annually.

The appearance of the reconstituted product is slightly pinkish beige.

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

The administration of a 10 fold overdose at a single injection site did not cause any reactions other than those mentioned in the section 4.6 ‘Adverse reactions’ except that the duration of local reactions was increased (up to 26 days).

4.11 Withdrawal period(s)

Not applicable

5. IMMUNOLOGICAL PROPERTIES

- ATCvet code QI07AI02
- Pharmacotherapeutic group: Immunologicals for Canidae – Live viral and inactivated bacterial vaccines for dogs.
- 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

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

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

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal 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 after reconstitution.

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

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 vial of lyophilisate and 1 vial of suspension
10 vials of lyophilisate and 10 vials of suspension
25 vials of lyophilisate and 25 vials of suspension
50 vials of lyophilisate and 50 vials of suspension
100 vials of lyophilisate and 100 vials of suspension
Not all pack sizes may be marketed.

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

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

VIRBAC
1ère avenue 2065m LID
06516 Carros
France

8. MARKETING AUTHORISATION NUMBER

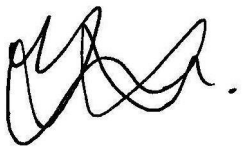
Vm 05653/5054

9. DATE OF FIRST AUTHORISATION

14 May 2012

10. DATE OF REVISION OF THE TEXT

March 2024



Approved: 19 March 2024