1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CANIXIN DHPPi lyophilisate and solvent 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%

Solvent

Water for injections	1 ml

Excipients:
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for injection.
Lyophilisate: White lyophilisate.
Solvent: Colourless 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;

Onset of immunity:
The onset of immunity has been demonstrated:

- From 3 weeks after the primary vaccination for CDV, CAV2 and CPV
- From 4 weeks after the primary vaccination for CPiV and CAV-1

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 or CAV-2.

After the annual booster, the duration of immunity lasts for 3 years for CDV, CAV-1, CAV-2 and CPV and 1 year for CPiV.
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

Safety and efficacy data are available which demonstrate that this vaccine can be mixed and administered with Virbac's Leptospira vaccine containing the strains *Leptospira interrogans* (serogroup Canicola serovar Canicola and serogroup Icterohaemorrhagiae serovar Icterohaemorrhagiae) or Virbac's rabies vaccine, if available.
No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except the products mentioned above. 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

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 1 year after the primary vaccination course.
Subsequent vaccinations are carried out at intervals of up to three years.
Annual revaccination is required for the CPiV component.
The appearance of the reconstituted product is slightly pink.

When active immunisation against leptospira is also required, Virbac's Leptospira vaccine can be used **instead** of the solvent. After reconstitution of one dose of the product with one dose of Virbac's Leptospira vaccine, shake gently (the reconstituted product is slightly pinkish beige) and administer immediately one dose of 1 ml subcutaneously according to the **same** vaccination schedule as above (annual revaccination required for the leptospira component).

When active immunisation against rabies is also required, **and if Virbac's rabies vaccine is available**, 1 dose of Virbac's rabies vaccine can be used instead of the solvent. Refer to the Virbac's rabies vaccine product information regarding vaccination scheme against rabies.

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 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

Pharmacotherapeutic group: Immunologicals for Canidae - Live viral vaccines for dogs.
ATCvet code: QI07AD04

To stimulate active immunity against canine distemper virus, canine adenovirus, canine parvoviruses, canine parainfluenza virus.

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

Solvent:
Water for injections

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal product, except those mentioned in 4.8.

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 solvent, both closed by a butyl-elastomer stopper and sealed with an aluminium cap, in a plastic or cardboard box.

Pack sizes:
1 vial lyophilisate and 1 vial solvent
5 vials lyophilisate and 5 vials solvent
10 vials lyophilisate and 10 vials solvent
25 vials lyophilisate and 25 vials solvent
50 vials lyophilisate and 50 vials solvent
100 vials lyophilisate and 100 vials solvent

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(S)

VPA10988/101/001

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 16/09/2016
Date of last renewal: 01/04/2021

10 DATE OF REVISION OF THE TEXT

05/10/2023