1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CANIXIN DHPPi lyophilisate and solvent for suspension for injection for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Once reconstituted, each dose of 1 ml contains:

Active substances:

Lyophilisate

Canine distemper virus (CDV), strain Lederle, live attenuated	$10^{3.0}$ - $10^{4.9}$ $CCID_{50}$*
Canine adenovirus type 2 (CAV-2), strain Manhattan, live attenuated	$10^{4.0}$ - $10^{6.0}$ $CCID_{50}$*
Canine parvovirus (CPV), strain Cornell 780916, live attenuated	$10^{5.0}$ - $10^{6.8}$ $CCID_{50}$*
Canine parainfluenza virus (CPiV), strain Manhattan, live attenuated	$10^{5.0}$- $10^{6.9}$ $CCID_{50}$*

* Cell culture infectious dose 50%

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
Solvent:
Water for injections

Lyophilisate: White lyophilisate.
Solvent: Colourless liquid.

3. CLINICAL INFORMATION

3.1 Target species

Dogs

3.2 Indications for use for each target species

For active immunisation of dogs 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.

Onset of immunity:
- From 3 weeks after the primary vaccination for CDV, CAV-2 and CPV
- From 4 weeks after the primary vaccination for CPiV and CAV-1

Duration of immunity:
After the primary vaccination course: one year.
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.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.
In susceptible puppies suspected to present low levels of maternal derived antibodies (i.e. born from non-vaccinated mothers, from large litters, poor feeders,...), an earlier immunisation may be recommended by the veterinarian (i.e. in case of early puppy socialisation, high risk environment,...) and the vaccination scheme should be adapted accordingly (see section 3.9).
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	Injection site swelling[1,2,3], Injection site oedema[2,3,4]

(1 to 10 animals / 100 animals treated):	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). In puppies of 6 weeks of age, swelling (≤ 2cm) sometimes associated with pain and sometimes followed by nodules (≤ 0.1cm), self-resolving within 2 weeks may be very commonly observed (refer to symptoms of overdose section).
[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

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.

3.9 Administration routes and dosage

After reconstitution of the lyophilisate with the solvent, shake gently (reconstituted product is slightly pink) 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.

When an early vaccination is recommended in susceptible puppies (see section 3.4), an additional injection from 6 weeks of age can be performed; followed 2 weeks later (from 8 weeks of age) by the usual vaccination scheme (2 injections performed at a 3-4 weeks interval).

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.

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).Refer to the Virbac's Leptospira's vaccine product information regarding vaccination scheme against *Leptospira*.

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.

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 Section 3.6 'Adverse events' except that the duration of local reactions was increased (up to 26 days). In puppies of 6 weeks of age, swelling (≤2cm) sometimes associated with pain and sometimes followed by nodules (≤0.1cm), self-resolving within 2 weeks may be very commonly observed.

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: QI07AD04

To stimulate active immunity against canine distemper virus, canine adenovirus, canine parvoviruses, canine parainfluenza virus.
In susceptible puppies at 6 weeks of age, safety of the vaccination has been established and benefit of the addition of one injection has been demonstrated based on the following points:
- for CPiv based on the reduction of excretion from 2 weeks after the first 2 injections
- for CDV, CAV-2, CAV-1, CPV2 and CPV2-c based on the presence of antibodies 2 weeks after one single injection.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product except solvent supplied for use with the veterinary medicinal product and except those mentioned in section 3.8 above.

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 solvent, 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 1ml solvent
5 x 1 dose lyophilisate and 5 x 1ml solvent
10 x 1 dose lyophilisate and 10 x 1ml solvent
25 x 1 dose lyophilisate and 25 x 1ml solvent
50 x 1 dose lyophilisate and 50 x 1ml solvent
100 x 1 dose lyophilisate and 100 x 1ml solvent

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)

VPA10988/101/001

8. DATE OF FIRST AUTHORISATION

16/09/2016

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

11/07/2025

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).