1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 1 ml contains:

Active substances:
Lyophilisate:
Canine parainfluenza virus (CPiV), strain Manhattan, live attenuated $10^{4.8}$– $10^{6.9}$ $CCID_{50}$*

* Cell culture infectious dose 50%

Suspension:
*Leptospira interrogans, s*erogroup Canicola, serovar Canicola, strain 601903, inactivated 4350 - 7330 U**
Leptospira interrogans, serogroup Icterohaemorrhagiae, serovar Icterohaemorrhagiae, strain 601895, inactivated 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:
Sucrose
Dipotassium phosphate
Potassium dihydrogen phosphate
Tryptone
Sodium hydroxide (for pH adjustment)
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:
- reduce respiratory clinical signs and viral excretion caused by canine parainfluenza virus;
- prevent mortality and reduce infection, clinical signs, kidney colonisation, renal lesions and urine shedding of *Leptospira* Canicola;
- reduce infection, clinical signs, kidney colonisation and urine shedding of *Leptospira* Icterohaemorrhagiae.

Onset of immunity:
- 4 weeks for CPiV,
- 5 weeks for *Leptospira* Canicola,
- 2 weeks for *Leptospira* Icterohaemorrhagiae.

Duration of immunity:
One year.
In the one-year duration of immunity studies there was no significant difference between vaccinated and control dogs in viral excretion for CPiV, in reduction of kidney colonisation for *Leptospira* Canicola and *Leptospira* Icterohaemorrhagiae, nor in renal lesions and urine shedding for *Leptospira* Canicola.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

3.5 Special precautions for use

Special precautions for safe use in the target species:

None.

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, Vomiting)
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersensitivity reaction[5] (e.g. Anaphylaxis, Allergic skin reaction such as Allergic oedema, Urticarial erythema, Allergic pruritus)

[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

Safety and efficacy data are available which demonstrate that this vaccine can be mixed and administered with 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 product 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

Subcutaneous use.

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.

Annual re-vaccination:
One booster injection of a single dose should be given 1 year after the second injection and annually thereafter.

When active immunisation against rabies is also required, and if Virbac's rabies vaccine is available, 1 dose of the veterinary medicinal product can be mixed with 1 dose of Virbac's rabies vaccine and 2 ml of mixed vaccines can be administered immediately subcutaneously. Refer to the Virbac's rabies vaccine veterinary medicinal product information regarding vaccination scheme against rabies.

The appearance of the reconstituted veterinary medicinal product is slightly yellowish 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 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: QI07AI08

To stimulate active immunity against canine parainfluenza virus and *Leptospira interrogans* serogroup Canicola and *Leptospira interrogans* serogroup Icterohaemorrhagiae in dogs.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product, except those mentioned in section 3.8.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: use immediately.
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 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.

5.5 Special precautions for the disposal of unused 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)

VPA10988/103/001

8. DATE OF FIRST AUTHORISATION

13/04/2017

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

31/10/2025

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).