1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CANIGEN Pi/L lyophilisate and suspension for suspension for injection for dogs (BE BG CY CZ EE EL ES FR HR HU IT LT LU LV NL PL PT RO SE SI SK)
CANIXIN Pi/L lyophilisate and suspension for suspension for injection for dogs (DK, IE, UK)
VIRBAGEN CANIS Pi/L lyophilisate and suspension for suspension for injection for dogs (AT, DE)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 1 ml contains:

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

* 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:
- 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:
The onset of immunity has been demonstrated from 4 weeks after the primary vaccination for CPiV, 5 weeks for *Leptospira* Canicola and 2 weeks for *Leptospira* Icterohaemorrhagiae.

Duration of immunity:

The duration of immunity lasts for one year after the primary vaccination for all components.
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.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Vaccinate healthy animals only.

4.5 Special precautions for use

Special precautions for use in animals:
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.

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 rabies vaccine, if available.
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.

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 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 product information regarding vaccination scheme against rabies.

The appearance of the reconstituted product is slightly yellowish 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 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 QI07AI08.
Pharmacotherapeutic group: Immunologicals for Canidae, live viral and inactivated bacterial vaccines for dogs.

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

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 anhydrous

Suspension:

Sucrose
Dipotassium phosphate
Potassium dihydrogen phosphate
Tryptone
Sodium hydroxide (for pH adjustment)
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: 2 years.
Shelf life after first opening the immediate packaging: use immediately.
Shelf life after reconstitution according to directions: use immediately.

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 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 2065 m LID
06516 Carros
France

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation:

Date of last renewal:

10. DATE OF REVISION OF THE TEXT