

**ANNEX I**  
**SUMMARY OF PRODUCT CHARACTERISTICS**

## 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//NI)

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:

Canine parainfluenza virus (CPiV), strain Manhattan, live attenuated  $10^{4.8} - 10^{6.9}$  CCID<sub>50</sub>\*

\* Cell culture infectious dose 50%

#### Suspension:

*Leptospira interrogans*, serogroup 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
<b>Lyophilisate:</b>
Gelatin
Potassium hydroxide
Lactose monohydrate
Glutamic acid
Potassium dihydrogen phosphate
Dipotassium phosphate
Water for injections
Sodium chloride
Disodium phosphate
<b>Suspension:</b>
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 <sup>1,2,3</sup> , Injection site oedema <sup>2,3,4</sup> Lethargy <sup>2</sup>
Rare (1 to 10 animals / 10,000 animals treated):	Injection site pain <sup>2,3</sup> , Injection site pruritus <sup>2,3</sup> Hyperthermia <sup>2</sup> , Anorexia <sup>2</sup> Digestive tract disorders <sup>2</sup> (e.g. Diarrhoea, Vomiting)
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersensitivity reaction <sup>5</sup> (e.g. Anaphylaxis, Allergic skin reaction such as Allergic oedema, Urticarial erythema, Allergic pruritus)

<sup>1</sup> ( $\leq 4$  cm)

<sup>2</sup> Transient

<sup>3</sup> Resolves spontaneously within 1 to 2 weeks.

<sup>4</sup> Slight, diffuse

<sup>5</sup> 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)**

**8. DATE OF FIRST AUTHORISATION**

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

**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 \(https://medicines.health.europa.eu/veterinary\)](https://medicines.health.europa.eu/veterinary).

**ANNEX III**  
**LABELLING AND PACKAGE LEAFLET**

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**Plastic or cardboard box containing 1 or 10 vials of lyophilisate and 1 or 10 vials of suspension**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

CANIGEN Pi/L lyophilisate and suspension for suspension for injection (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 (DK, IE, UK/NI)

VIRBAGEN CANIS Pi/L lyophilisate and suspension for suspension for injection (AT, DE)

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each dose of 1 ml contains:

**Active substances:**

Lyophilisate:

Canine parainfluenza virus (CPiV), strain Manhattan, live attenuated  $10^{4.8}$ –  $10^{6.9}$  CCID<sub>50</sub>\*

\* Cell culture infectious dose 50%

Suspension:

*Leptospira interrogans*, serogroup Canicola, serovar Canicola, strain 601903, inactivated  
4350 - 7330 U\*\*

*Leptospira interrogans*, serogroup Icterohaemorrhagiae, serovar Icterohaemorrhagiae, strain 601895,  
inactivated 4250 - 6910 U\*\*

Canine parainfluenza virus, strain Manhattan, live  $10^{4.8}$ –  $10^{6.9}$  CCID<sub>50</sub>\*

\* Cell culture infectious dose 50%

Suspension:

*Leptospira interrogans*, serogroup 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

**3. PACKAGE SIZE**

1 × 1 dose lyophilisate and 1 × 1 ml suspension

10 × 1 dose lyophilisate and 10 × 1 ml suspension

**4. TARGET SPECIES**

Dogs.

**5. INDICATIONS**

**6. ROUTES OF ADMINISTRATION**

Subcutaneous use.

**7. WITHDRAWAL PERIODS**

**8. EXPIRY DATE**

Exp. {mm/yyyy}

Once opened use immediately.

Once reconstituted use immediately.

**9. SPECIAL STORAGE PRECAUTIONS**

Store and transport refrigerated.

Protect from light.

Do not freeze.

**10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”**

Read the package leaflet before use.

**11. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

For animal treatment only.

**12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”**

Keep out of the sight and reach of children.

**13. NAME OF THE MARKETING AUTHORISATION HOLDER**

VIRBAC

**14. MARKETING AUTHORISATION NUMBERS**

**15. BATCH NUMBER**

Lot {number}

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**Plastic or cardboard box containing 25, 50 or 100 vials of lyophilisate and 25, 50 or 100 vials of suspension**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

CANIGEN Pi/L lyophilisate and suspension for suspension for injection (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 (DK, IE, UK/NI)

VIRBAGEN CANIS Pi/L lyophilisate and suspension for suspension for injection (AT, DE)

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each dose of 1 ml contains:

**Active substances:**

Lyophilisate:

Canine parainfluenza virus (CPiV), strain Manhattan, live attenuated  $10^{4.8} - 10^{6.9}$  CCID<sub>50</sub>\*

\* Cell culture infectious dose 50%

Suspension:

*Leptospira interrogans*, serogroup 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

**3. PACKAGE SIZE**

25 × 1 dose lyophilisate and 25 × 1 ml suspension

50 × 1 dose lyophilisate and 50 × 1 ml suspension

100 × 1 dose lyophilisate and 100 × 1 ml suspension

**4. TARGET SPECIES**

Dogs.

**5. INDICATIONS**

**6. ROUTES OF ADMINISTRATION**

Subcutaneous use.

**7. WITHDRAWAL PERIODS**

**8. EXPIRY DATE**

Exp. {mm/yyyy}

Once opened use immediately.

Once reconstituted use immediately.

**9. SPECIAL STORAGE PRECAUTIONS**

Store and transport refrigerated.

Protect from light.

Do not freeze.

**10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”**

Read the package leaflet before use.

**11. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

For animal treatment only.

**12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”**

Keep out of the sight and reach of children.

**13. NAME OF THE MARKETING AUTHORISATION HOLDER**

VIRBAC

**14. MARKETING AUTHORISATION NUMBERS**

**15. BATCH NUMBER**

Lot {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

**Vial with lyophilisate**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

CANIGEN Pi/L (BE BG CY CZ EE EL ES FR HR HU IT LT LU LV NL PL PT RO SE SI SK)

CANIXIN Pi/L (DK, IE, UK/NI)

VIRBAGEN CANIS Pi/L (AT, DE)



**2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES**

Pi

1 dose

**3. BATCH NUMBER**

Lot {number}

**4. EXPIRY DATE**

Exp. {mm/yyyy}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

**Vial with suspension**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

CANIGEN Pi/L (BE BG CY CZ EE EL ES FR HR HU IT LT LU LV NL PL PT RO SE SI SK)

CANIXIN Pi/L (DK, IE, UK/NI)

VIRBAGEN CANIS Pi/L (AT, DE)



**2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES**

L

1 ml

**3. BATCH NUMBER**

Lot {number}

**4. EXPIRY DATE**

Exp. {mm/yyyy}

**B. PACKAGE LEAFLET**

## PACKAGE LEAFLET

### 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/NI)

VIRBAGEN CANIS Pi/L lyophilisate and suspension for suspension for injection for dogs (AT, DE)

### 2. 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<sub>50</sub>\*

\* Cell culture infectious dose 50%

##### Suspension:

*Leptospira interrogans*, serogroup 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

Lyophilisate: White lyophilisate.

Suspension: Translucent liquid.

### 3. Target species

Dogs.

### 4. Indications for use

#### 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*.

## **5. Contraindications**

None.

## **6. Special warnings**

### Special warnings:

Vaccinate healthy animals only.

### 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.

### Pregnancy and lactation:

Do not use during pregnancy and lactation.

### 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.

### Overdose:

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

### Major incompatibilities:

Do not mix with any other veterinary medicinal product, except those mentioned in section "Interaction with other medicinal products and other forms of interaction".

## **7. Adverse events**

Dogs:

Common (1 to 10 animals / 100 animals treated):
Injection site swelling <sup>1,2,3</sup> , Injection site oedema <sup>2,3,4</sup> Lethargy <sup>2</sup>
Rare (1 to 10 animals / 10,000 animals treated):
Injection site pain <sup>2,3</sup> , Injection site pruritus (itching) <sup>2,3</sup> Hyperthermia <sup>2</sup> , Anorexia <sup>2</sup> Digestive tract disorders <sup>2</sup> (e.g. Diarrhoea, Vomiting)
Very rare (<1 animal / 10,000 animals treated, including isolated reports):

Hypersensitivity reaction<sup>5</sup> (e.g. Anaphylaxis (severe form of allergic reaction), Allergic skin reaction such as Allergic oedema (swelling), Urticarial erythema (redness), Allergic pruritus (itching))

<sup>1</sup> ( $\leq 4$  cm).

<sup>2</sup> Transient.

<sup>3</sup> Resolves spontaneously within 1 to 2 weeks.

<sup>4</sup> Slight, diffuse.

<sup>5</sup> Appropriate symptomatic treatment should be administered without delay.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or its local representative using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

## **8. Dosage for each species, routes and method of administration**

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.

## **9. Advice on correct administration**

The appearance of the reconstituted veterinary medicinal product is slightly yellowish beige.

## **10. Withdrawal periods**

Not applicable.

## **11. Special storage precautions**

Keep out of the sight and reach of children.

Store and transport refrigerated (2 °C – 8 °C).

Protect from light.

Do not freeze.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: use immediately.  
Shelf life after reconstitution according to directions: use immediately.

## **12. Special precautions for disposal**

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

## **13. Classification of veterinary medicinal products**

Veterinary medicinal product subject to prescription.

## **14. Marketing authorisation numbers and pack sizes**

Plastic or cardboard box of 1 x 1 dose lyophilisate and 1 x 1 mL suspension  
Plastic or cardboard box of 10 x 1 dose lyophilisate and 10 x 1 mL suspension  
Plastic or cardboard box of 25 x 1 dose lyophilisate and 25 x 1 mL suspension  
Plastic or cardboard box of 50 x 1 dose lyophilisate and 50 x 1 mL suspension  
Plastic or cardboard box of 100 x 1 dose lyophilisate and 100 x 1 mL suspension

Not all pack sizes may be marketed.

## **15. Date on which the package leaflet was last revised**

Detailed information on this veterinary medicinal product is available in the [Union Product Database \(https://medicines.health.europa.eu/veterinary\)](https://medicines.health.europa.eu/veterinary).

## **16. Contact details**

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse events:

VIRBAC  
1<sup>ère</sup> avenue 2065 m LID.  
06516 Carros  
France

Local representatives and contact details to report suspected adverse events:

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

