

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **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:

Live attenuated canine parainfluenza virus (CPiV), 10<sup>4.8</sup>– 10<sup>6.9</sup> CCID<sub>50</sub>\*  
Manhattan strain

\* 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 ( $\leq 4$  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 2065m LID  
06516 Carros  
France

### **8. MARKETING AUTHORISATION NUMBER**

Vm 05653/4209

### **9. DATE OF FIRST AUTHORISATION**

28 March 2017

### **10. DATE OF REVISION OF THE TEXT**

February 2022

Approved 14 February 2022

A handwritten signature in black ink, consisting of a stylized, cursive initial followed by the name "Hunter." with a period.