

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

CANIXIN Pi/L lyophilisate and suspension for suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose of 1 ml contains:

Active substances:

Lyophilisate:

Canine parainfluenza virus (CPIV), strain Manhattan, live attenuated $10^{4.8} - 10^{6.9}$ CCID₅₀*

* 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 $10^{4.8} - 10^{6.9}$ CCID₅₀*

* 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

Vm 05653/3052

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

CANIXIN Pi/L lyophilisate and suspension for suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose of 1 ml contains:

Active substances:

Lyophilisate:

Canine parainfluenza virus (CPiV), strain Manhattan, live attenuated $10^{4.8} - 10^{6.9}$ CCID₅₀*

* 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

Vm 05653/3052

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial with lyophilisate

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CANIXIN Pi/L



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

CANIXIN Pi/L



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

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

2. Composition

Each dose of 1 ml contains:

Active substances:

Lyophilisate:

Canine parainfluenza virus (CPiV), strain Manhattan, live attenuated $10^{4.8} - 10^{6.9}$ CCID₅₀*

* 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 ^{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 (itching) ^{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 (severe form of allergic reaction), Allergic skin reaction such as Allergic oedema (swelling), Urticarial erythema (redness), Allergic pruritus (itching))

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 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:

E-mail: adverse.events@vmd.gov.uk

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

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

Vm 05653/3052

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. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

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

Virbac
1ère avenue 2065m 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.

17. Other information

POM-V

Approved 08 December 2025

Gavin Hall