LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

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 for dogs

2. STATEMENT OF ACTIVE SUBSTANCES

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

3. PHARMACEUTICAL FORM

Lyophilisate and suspension for suspension for injection.

4. PACKAGE SIZE

1 vial of lyophilisate and 1 vial of suspension
10 vials of lyophilisate and 10 vials of suspension

5. TARGET SPECIES

Dog.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP:
Once reconstituted use immediately.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated.
Protect from light.
Do not freeze.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

VIRBAC
1ère avenue 2065m LID
06516 Carros
France

16. MARKETING AUTHORISATION NUMBER(S)

Vm 05653/4209

17. MANUFACTURER'S BATCH NUMBER

Batch :{number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

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 for dogs

2. STATEMENT OF ACTIVE SUBSTANCES

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

3. PHARMACEUTICAL FORM

Lyophilisate and suspension for suspension for injection.

4. PACKAGE SIZE

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

5. TARGET SPECIES

Dog.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP:
Once reconstituted use immediately.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated.
Protect from light.
Do not freeze.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

VIRBAC
1ère avenue 2065m LID
06516 Carros
France

16. MARKETING AUTHORISATION NUMBER(S)

Vm 05653/4209

17. MANUFACTURER'S BATCH NUMBER

Batch :{number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial with lyophilisate

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CANIXIN Pi/L

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Pi

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

1 dose

4. ROUTE(S) OF ADMINISTRATION

SC

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Batch: {number}

7. EXPIRY DATE

EXP:

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial with suspension

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CANIXIN Pi/L suspension for dogs

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

L

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

1 ml

4. ROUTE(S) OF ADMINISTRATION

SC

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Batch: {number}

7. EXPIRY DATE

EXP:

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
CANIXIN Pi/L lyophilisate and suspension for suspension for injection for dogs

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder and manufacturer responsible for batch release:
VIRBAC
1ère avenue 2065m LID
06516 Carros
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

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

Lyophilisate: White lyophilisate.
Suspension: Translucent liquid.

4. INDICATION(S)

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.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

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).

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 inform your veterinary surgeon.

Alternatively you can report via your national reporting system {national system details}.

7. TARGET SPECIES

Dog.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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.

9. ADVICE ON CORRECT ADMINISTRATION

The appearance of the reconstituted product is slightly yellowish beige.

10. WITHDRAWAL PERIOD(S)

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 after the expiry date which is stated on the label after EXP.
Use immediately after reconstitution.

12. SPECIAL WARNING(S)

Special warnings for each target species:
Vaccinate healthy animals only.

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.

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. 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.

Overdose (symptoms, emergency procedures, antidotes):
The administration of a 10 fold overdose at a single injection site did not cause any reactions other than those mentioned in the section on adverse reactions except that the duration of local reactions was increased (up to 26 days).

Incompatibilities:
Do not mix the vaccine with any other veterinary medicinal product, except those mentioned in the section 'Interaction with other medicinal products and other forms of interaction'.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

February 2022

15. OTHER INFORMATION

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.

Approved 14 February 2022