LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box containing 1 or 10 vials of suspension

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CANIXIN L suspension for injection for dogs

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose of 1 ml contains:

Active substances:
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

Suspension for injection.

4. PACKAGE SIZE

1 vial of suspension
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:

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 05653/4208

17. MANUFACTURER'S BATCH NUMBER

Batch :{number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box containing 25, 50 or 100 vials of suspension

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CANIXIN L suspension for injection for dogs

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose of 1 ml contains:

Active substances:
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

Suspension for injection.

4. PACKAGE SIZE

25 vials of suspension
50 vials of suspension
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:

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 05653/4208

17. MANUFACTURER'S BATCH NUMBER

Batch :{number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial with suspension

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CANIXIN L suspension for injection 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 L 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 L suspension for injection for dogs

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

Each dose of 1 ml contains:

Active substances:
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

Suspension: Translucent liquid.

4. INDICATION(S)

For active immunisation of dogs from 8 weeks of age to:
- 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 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 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

Shake gently and administer immediately one dose of 1 ml subcutaneously according to the following vaccination schedule:

<u>Primary vaccination course:</u>
- first injection from 8 weeks of age

- second injection 3 or 4 weeks later.

When active immunisation against CDV, CAV, CPV and CPiV is required, one dose of the product can be used to reconstitute one dose of Virbac's freeze-dried vaccines containing CDV, CAV-2, CPV and CPiV components. After reconstitution, shake gently (the reconstituted product is slightly pinkish beige) and administer immediately one dose of 1 ml subcutaneously according to the same vaccination schedule: 2 injections 3 to 4 weeks apart from 8 weeks of age.
When active immunisation against rabies is also required, and if Virbac's rabies vaccine is available, 1 dose of the product alone or mixed as above 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.

Annual re-vaccination:
One booster injection of a single dose should be given 1 year after the second injection and annually thereafter.

9. ADVICE ON CORRECT ADMINISTRATION

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.

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 vaccines against canine distemper virus (CDV), canine adenovirus (CAV), canine parvovirus (CPV), canine parainfluenza virus (CPiV) and rabies, if available.
No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except the products mentioned above. 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):
Not applicable.

Incompatibilities:
Do not mix 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 ml of suspension closed by a butyl-elastomer stopper and sealed with an aluminium cap, in a plastic or cardboard box.

Pack sizes:
1 vial of suspension
10 vials of suspension
25 vials of suspension
50 vials of suspension
100 vials of suspension.

Not all pack sizes may be marketed.

Approved 14 February 2022