SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Canigen L 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 L suspension for injection for dogs (DK IE UK/NI)
Virbagen Canis L suspension for injection for dogs (AT DE)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

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

Excipients:

Qualitative composition of excipients and other constituents
Sodium hydroxide (for pH adjustment)
Sucrose
Dipotassium phosphate
Potassium dihydrogen phosphate
Tryptone
Water for injections

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:
- 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.

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:

Not applicable.

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[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[2,3] Hyperthermia[2], Anorexia[2] Digestive tract disorder (e.g. Diarrhoea, Vomiting)[2]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersensitivity reaction (e.g. Anaphylaxis, Allergic skin reaction such as Allergic oedema, Urticarial erythema, Allergic pruritus)[5]

[1] (≤ 4 cm).
[2] Transient.
[3] Any such local reaction resolves spontaneously within 1 to 2 weeks.
[4] Slight diffuse.
[5] In such case, appropriate symptomatic treatment should be administered.

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 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.

3.9 Administration routes and dosage

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.

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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Not applicable.

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: QI07AB01.

To stimulate active immunity against *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 above.

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.

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 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.

5.5 Special precautions for the disposal of unused veterinary 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).

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

Canigen L 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 L suspension for injection (DK IE UK/NI)
Virbagen Canis L suspension for injection (AT DE)

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. PACKAGE SIZE

1 x 1 ml suspension
10 x 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.

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

Box containing 25, 50 or 100 vials of suspension

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Canigen L 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 L suspension for injection (DK IE UK/NI)
Virbagen Canis L suspension for injection (AT DE)

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. PACKAGE SIZE

25 x 1 ml suspension
50 x 1 ml suspension
100 x 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

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 suspension

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Canigen L (BE BG CY CZ EE EL ES FR HR HU IT LT LU LV NL PL PT RO SE SI SK)
Canixin L (DK IE UK/NI)
Virbagen Canis L (AT DE)

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Leptospira
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 L 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 L suspension for injection for dogs (DK IE UK/NI)
Virbagen Canis L suspension for injection for dogs (AT DE)

2. Composition

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

Translucent liquid.

3. Target species

Dogs.

4. Indications for use

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. 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 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.

Major 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'.

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 (elevated body temperature)[2], Anorexia[2] Digestive tract disorder (e.g. Diarrhoea, Vomiting)[2]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Hypersensitivity reaction (e.g. Anaphylaxis (severe allergic reaction), Allergic skin reaction such as Allergic oedema, Urticarial erythema (raised red rash), Allergic pruritus)[5]

[1] (≤ 4 cm)
[2] Transient
[3] Any such local reaction resolves spontaneously within 1 to 2 weeks.
[4] Slight diffuse
[5] In such case, appropriate symptomatic treatment should be administered.

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 the local representative of the marketing

authorisation holder 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

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.

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 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.

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

1 x 1 ml vial of suspension
10 x 1 ml vial of suspension
25 x 1 ml vial of suspension
50 x 1 ml vial of suspension
100 x 1 ml vial of 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).

16. Contact details

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

VIRBAC
1ère avenue 2065 m LID
06516 Carros
France

Local representatives and contact details to report suspected adverse reactions:

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