SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Canixin L suspension for injection for dogs

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

Vm 05653/3029

8. DATE OF FIRST AUTHORISATION

03 April 2017

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

June 2024

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).

Gavin Hall
Approved: 22 June 2024