SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Canigen Lepto 2 suspension for injection for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml dose contains:

Active substances:
Leptospira interrogans serogroup Canicola, serovar Portland-vere, strain Ca-12-000, Inactivated:
990 – 1755 Units*
Leptospira interrogans serogroup Icterohaemorrhagiae, serovar Copenhageni, strain 820K, Inactivated: 699 – 1277 Units*

* Antigenic mass ELISA Units.

Excipients:

Qualitative composition of excipients and other constituents
Sodium chloride
Potassium chloride
Potassium dihydrogen phosphate
Disodium phosphate dihydrate
Water for injections

Colourless suspension.

3. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each target species

For the active immunisation of dogs to reduce infection with *Leptospira interrogans* serogroup Canicola and *Leptospira interrogans* serogroup Icterohaemorrhagiae.

Specific claims:
Duration of immunity: at least 1 year.
This veterinary medicinal product significantly reduces the number of animals which develop a urinary tract infection which can predispose to development of a carrier condition after *L.* Canicola and *L.* Icterohaemorrhagiae infection.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

The vaccine may not be effective in dogs incubating the disease at the time of vaccination.
Animals that have received the corresponding anti-serum or immunosuppressive drugs should not be vaccinated until an interval of at least 4 weeks has elapsed.
A good immune response is reliant on the reaction of an immunogenic agent and a fully competent immune system. Immunogenicity of the vaccine antigen will be reduced by poor storage or inappropriate administration.
Immunocompetence of the animal may be compromised by a variety of factors including poor health, nutritional status, genetic factors, concurrent drug therapy and stress.

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:

Very common (>1 animal / 10 animals treated):	Injection site swelling[1].
Rare (1 to 10 animals / 10 000 animals treated):	Elevated temperature[2].
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Injection site reaction. Hypersensitivity reaction (e.g. lethargy, facial oedema, pruritus, vomiting or diarrhoea)[3], anaphylaxis (e.g. dyspnoea, collapse)[3,4]. Lethargy[5], anorexia[5]. Immune-mediated haemolytic anaemia, immune-mediated thrombocytopenia, immune-mediated

	polyarthritis.

[1] Up to 5 cm in diameter for up to 4 days. This swelling may be hard and painful, but this will diminish gradually and disappear after 2-3 weeks.
[2] Transient.
[3] May occur shortly after vaccination.
[4] May be life-threatening. If such reactions occur, appropriate treatment is recommended.
[5] Mild.

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:
Can be used during pregnancy.

The vaccine has been shown to be safe for use in pregnant bitches which have previously been vaccinated with Canigen Lepto 2.

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 with live vaccines in the Canigen range containing canine distemper virus (strain Onderstepoort), canine adenovirus type 2 (strain Manhattan LPV3), canine parvovirus (strain 154) and/or canine parainfluenza virus (strain Cornell) components authorised for subcutaneous administration.

Safety and efficacy data are available which demonstrate that this vaccine can be administered on the same day but not mixed with Canigen Rabies, the inactivated rabies (strain Pasteur RIV) vaccine in the Canigen range.

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 made on a case by case basis.

3.9 Administration routes and dosage

Subcutaneous use.
Administer 1 dose (1 ml) per animal.

Allow the vaccine to reach room temperature (15 °C – 25 °C) before use.
Sterile injection equipment should be used.
Primary vaccination course:
All dogs not previously vaccinated should be vaccinated twice, 2 – 4 weeks apart. Puppies should be at least 6 weeks of age before they receive the first vaccination.

Revaccination:
A single annual booster dose is recommended.

Canigen Lepto 2 may be used to reconstitute Canigen DHPPi, DHP, Pi or Parvo-C as indicated in the appropriate package leaflets.

For more detailed advice on vaccination programmes and how the product may be used in conjunction with other Canigen dog vaccines under specific circumstances, contact the company/distributor or refer to the support literature.

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

No symptoms other than at a single dose (see section 3.6).

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.

Strains of *Leptospira interrogans* serogroups Canicola and Icterohaemorrhagiae are responsible for leptospirosis in dogs. The active ingredients of the vaccine *Leptospira interrogans* Canicola, strain Ca-12-000 and *Leptospira interrogans* Icterohaemorrhagiae, strain 820K stimulate active immunity against these serogroups.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product, except those mentioned in section 3.8 above where their combined use is authorised.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 21 months.
Shelf life after first opening the immediate packaging: use immediately.

5.3 Special precautions for storage

Store in a refrigerator (2 °C – 8 °C).

Do not freeze.
Store in the original package.
Protect from light.

5.4 Nature and composition of immediate packaging

Type I glass vial(s) of 1 ml closed with a halogenobutyl rubber stopper and sealed with a coded aluminium cap.

Pack sizes:
Cardboard box with 1, 10 or 50 vials of 1 ml (1 dose).
Plastic box with 10 or 50 vials of 1 ml (1 dose).

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater.

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

Intervet International B.V.

7. MARKETING AUTHORISATION NUMBERS

Vm 06376/5060
Vm 06376/3060

8. DATE OF FIRST AUTHORISATION

27 August 2003

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

May 2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

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

Approved 20 May 2026

Gavin Hall