

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
PLASTIC BOX with 10 x 1 ml or 50 x 1 ml vials
(information included on front of inlay, and front and back seal labels)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Canigen Lepto 2 suspension for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Per dose (1 ml):

- Inactivated *Leptospira interrogans*, serogroup Canicola: 990 – 1755 Units*
- Inactivated *Leptospira interrogans*, serogroup Icterohaemorrhagiae: 699 – 1277 Units*

*Antigenic mass ELISA units.

3. PHARMACEUTICAL FORM

Suspension for injection.

4. PACKAGE SIZE

10 x 1 ml

50 x 1 ml

5. TARGET SPECIES

Dogs.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous use.

Read package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s): Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

Read package leaflet before use.

SECTIONS 10 – 17 ARE PRINTED ON THE FRONT AND BACK SEAL LABELS

10. EXPIRY DATE

EXP end of: {month/year}

Once broached, use immediately.

11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator.

Do not freeze.

Store in the original package. Protect from light.

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.

POM-V

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

MA holder

MSD Animal Health UK Ltd.

Walton Manor, Walton

Milton Keynes

MK7 7AJ

Distributor:

Virbac Ltd.
Woolpit Business Park
Windmill Avenue, Woolpit
Bury St. Edmunds
Sussex
IP30 9UP

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4493

17. MANUFACTURER'S BATCH NUMBER

Batch: {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
CARDBOARD BOX with 1 x 1 ml, 10 x 1 ml or 50 x 1 ml vials

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Canigen Lepto 2 suspension for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Per dose (1 ml):

Inactivated *Leptospira interrogans*, serogroup Canicola: 990 – 1755 Units*

Inactivated *Leptospira interrogans*, serogroup Icterohaemorrhagiae: 699 – 1277
Units*

*Antigenic mass ELISA units.

3. PHARMACEUTICAL FORM

Suspension for injection.

4. PACKAGE SIZE

1 x 1 ml

10 x 1 ml

50 x 1 ml

5. TARGET SPECIES

Dogs.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous use.

Read package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

Read package leaflet before use.

10. EXPIRY DATE

EXP end of: {month/year}

Once broached, use immediately

11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator.

Do not freeze.

Store in the original package. Protect from light.

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

Disposal: Read package leaflet before use.

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

For animal treatment only.

POM-V

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

MA holder

MSD Animal Health UK Ltd.

Walton Manor, Walton

Milton Keynes

MK7 7AJ

Distributor

Virbac Ltd.
Woolpit Business Park
Windmill Avenue, Woolpit
Bury St. Edmunds
Sussex, IP30 9UP

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4493

17. MANUFACTURER'S BATCH NUMBER

Batch: {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING
UNITS
LABEL of 1 ml vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Canigen Lepto 2



2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

L. interrogans Canicola: 990 – 1755 Units/ml

L. interrogans Icterohaemorrhagiae: 699 – 1277 Units/ml

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

1 ml

4. ROUTE(S) OF ADMINISTRATION

SC

5. WITHDRAWAL PERIOD(S)

Withdrawal period(s): Not applicable.

6. BATCH NUMBER

Batch: {number}

7. EXPIRY DATE

EXP end of: {month/year}

Once broached, use immediately.

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

Read package leaflet before use.

POM-V

Vm 01708/4493

Package leaflet text for carton presentations and package leaflet text included on inside of plastic tray inlay.

**PACKAGE LEAFLET FOR:
Canigen Lepto 2 suspension for injection**

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

Marketing authorisation holder

MSD Animal Health UK Ltd.
Walton Manor, Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

Manufacturer responsible for batch release:

Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Canigen Lepto 2 suspension for injection

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

Each 1 ml dose contains:

Active substances:

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

* Antigenic mass ELISA Units

Colourless suspension.

4. INDICATION(S)

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

Specific claims.

The duration of immunity induced by the vaccine was established as at least one year.

Canigen Lepto 2 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.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

A transient rise in body temperature post-vaccination has been observed in rare cases during the clinical safety studies.

Dogs may show local reactions after injection in very rare cases, according to spontaneous pharmacovigilance reports. A diffuse swelling, up to 5 cm in diameter, may be observed at the site of injection for up to 4 days. Occasionally this swelling may be hard and painful, but this will diminish gradually and disappear after 2-3 weeks.

A transient acute hypersensitivity reaction - with signs that may include lethargy, facial oedema, pruritus, vomiting or diarrhoea - may occur shortly after vaccination in very rare cases. Such reactions may evolve to a more severe condition (anaphylaxis), which may be life-threatening with additional signs like dyspnoea or collapse. If such reactions occur appropriate treatment is recommended.

Mild systemic signs such as lethargy and anorexia were reported very rarely.

Clinical signs of immune-mediated haemolytic anaemia, immune-mediated thrombocytopenia, or immune-mediated polyarthritis have been reported in very rare cases.

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.

7. TARGET SPECIES

Dogs.

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

Subcutaneous use.

Administer 1 dose (1 ml) per animal.

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

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.

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

9. ADVICE ON CORRECT ADMINISTRATION

Allow the vaccine to reach room temperature (15 °C – 25 °C) before use. Sterile injection equipment should be used.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store in a refrigerator (2 °C – 8 °C). Do not freeze.

Store in the original package.

Protect from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the label and outer packaging after 'EXP end of'. The expiry date refers to the last day of that month.

Shelf-life after first opening the container: use immediately.

12. SPECIAL WARNING(S)

Special warnings for each target species:

Vaccinate healthy animals only.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

In the case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for use in animals

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.

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.

Interactions 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 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. 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.

Overdose (symptoms, emergency procedures, antidotes):

No symptoms other than those at single dose.

Incompatibilities:

Do not mix with any other veterinary medicinal product except the vaccines mentioned above where their combined use is authorised.

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

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

Any unused veterinary medicinal product or waste material 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

July 2021

15. OTHER INFORMATION

For animal treatment only.

Pack sizes

Plastic box with 10 or 50 vials of 1 ml (1 dose).

Cardboard box with 1, 10 or 50 vials of 1 ml (1 dose).

Not all pack sizes may be marketed.

POM-V

To be supplied only on veterinary prescription.

MA number: Vm 01708/4493

Distributor

Virbac Ltd.

Woolpit Business Park

Windmill Avenue, Woolpit

Bury St. Edmunds

Suffolk, IP30 9UP

Approved 22 July 2021

