PARTICULARS TO APPEAR ON THE OUTER PACKAGE- Box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VIRBAGEN L

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Active ingredients: formula and titre per dose

- *Leptospira canicola*
  - titre before inactivation 833.10^6 bacteria/ml

……

- *Leptospira icterohaemorrhagiae* 833.10^6 bacteria/ml
  - titre before inactivation

……

0.038 ml of each, in buffered isotonic solution with residual culture medium.

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

10x1ml
50x1ml

5. TARGET SPECIES

Dogs

6. INDICATION(S)

For the active immunisation of dogs from 8 weeks of age to reduce clinical signs of disease. A serological response occurs by 3weeks after the second dose.

The duration of protection lasts 12 months after immunisation.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Shake well before use.

Primary vaccination

-Puppies of 8-9 weeks of age can be subcutaneously administered one dose of 1ml of VIRBAGEN L followed by another one 3-4 weeks later but never before the age of 12 weeks.

-Puppies older than 9 weeks can be subcutaneously administered one dose of VIRBAGEN L followed by another one 3-4 weeks later.

Booster vaccination

Annual revaccination with a single subcutaneous 1ml dose of VIRBAGEN L

8 WITHDRAWAL PERIOD.

9. SPECIAL WARNING(S), IF NECESSARY

Do not vaccinate females during pregnancy.

Read insert leaflet carefully before use.

10. EXPIRY DATE

EXP:

11. SPECIAL STORAGE CONDITIONS

Store and transport in the original package at a temperature of 4°C ± 2°C. Protect from light. Do not freeze.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE *[Distribution category]*

For animal treatment only

U.K. authorised veterinary medicinal product.

POM-V

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 - 2065 m – L.I.D.
06516 Carros Cedex
France

16. MARKETING AUTHORISATION NUMBER(S)

Vm 05653/4047 To be supplied only on veterinary prescription.

17. MANUFACTURER’S BATCH NUMBER

Batch

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS - Syringe

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VIRBAGEN L

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Leptospira canicola, Leptospira icterohaemorrhagiae 833.10^6 bacteria/ml

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

1 dose

4. ROUTE(S) OF ADMINISTRATION

Subcutaneous injection

5. WITHDRAWAL PERIOD

6. BATCH NUMBER

Batch:

7. EXPIRY DATE

EXP:

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only

PACKAGE LEAFLET FOR:

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

Virbac
1ère avenue - 2065 m – L.I.D.
06516 Carros Cedex
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

VIRBAGEN L

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

Active ingredients: formula and titre per dose

- *Leptospira canicola*
  - titre before inactivation
    …… 833.10^6 bacteria/ml
- *Leptospira icterohaemorrhagiae*
  - titre before inactivation
    …… 833.10^6 bacteria/ml

4. INDICATION(S)

For the active immunisation of dogs from 8 weeks of age to reduce clinical signs of disease.
A serological response occurs by 3 weeks after the second dose.
The duration of protection lasts 12 months after immunisation.

5. CONTRAINDICATIONS

Do not vaccinate females during pregnancy.

6. ADVERSE REACTIONS

Transient itching, pain and/or swelling may occur at the injection site.

Occasional hypersensitivity reactions may occur but the incidence of these is rare. If anaphylactic reactions should occur, immediately administer corticotherapy (if possible, high doses by I.V. route) or antihistamines associated with usual treatment against anaphylactic shock.

7. TARGET SPECIES

Dogs

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

Shake well before use.

Primary vaccination

- Puppies of 8-9 weeks of age can be subcutaneously administered one dose of 1 ml of VIRBAGEN L followed by another one 3-4 weeks later but never before the age of 12 weeks.
- Puppies older than 9 weeks can be subcutaneously administered one dose of 1 ml of VIRBAGEN L followed by another one 3-4 weeks later.

Booster vaccination

Annual revaccination with a single subcutaneous 1 ml dose of VIRBAGEN® L.

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD(S)

11. SPECIAL STORAGE PRECAUTIONS

Store and transport in the original package at a temperature of 4°C ± 2°C. Protect from light. Do not freeze.

12. SPECIAL WARNING(S)

The active ingredients of the vaccine are inactivated but normal precautions should be taken to avoid contact with the skin and self-injection. In the event of accidental self-injection, seek medical advice immediately.

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 products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

POM-V U.K. authorised veterinary medicinal product.

Vm 05653/4047

Approved: 17 October 2017