SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE IMMUNOLOGICAL VETERINARY MEDICINAL PRODUCT

VIRBAGEN L

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredients: formula and titre per dose

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

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

……

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

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Suspension for injection

4. CLINICAL PARTICULARS

4.1 Target species

Dogs

4.2 Indications for use, specifying the target species

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.

4.3 Contraindications

Do not vaccinate females during pregnancy.

4.4 Special warnings

None

4.5 Special precautions for use

i. Special precautions for use in animals

The vaccine should be administered in accordance with the usual aseptic conditions for vaccination.
It is recommended that animals be treated for intestinal parasites at least 10 days prior to vaccination.
Vaccinate only healthy dogs.
Avoid exposure of the animal to infection for 21 days following vaccination

ii. Special precautions for the person administering the veterinary medicinal product to animals

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.

4.6 Adverse reactions (frequency and seriousness)

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.

4.7 Use during pregnancy, lactation or lay

Do not use in pregnant animals.

4.8 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 canine distemper, canine adenovirus, canine parovirus and canine parainfluenza-virus vaccines.
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.

4.9 Amounts to be administered and administration route

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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Transient itching, pain and/or swelling similar to that described in section 4.6. may occur at the site of injection.

4.11 Withdrawal period

Not applicable

5. IMMUNOLOGICAL PROPERTIES

ATC Vet Code: QI07AB01

To stimulate active immunity against *Leptospira canicola* and *Leptospira ictero-haemorrhagiae.*

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose
Potassium hydrogen phosphate
Potassium dihydrogen phosphate
Tryptone
Water for injection

6.2 Incompatibilities

Safety and efficacy data are available which demonstrate that this vaccine can be mixed and administered with live canine distemper, canine adenovirus, canine parovirus and canine parainfluenza-virus vaccines. Do not mix with any other veterinary medicinal product.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 24 months
Shelf-life after first opening the immediate packaging: use immediately

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Containers
Insulin-type vial - 3 ml - Diameter 16, 25/38.5.
Neutral borosilicate type I glass complying with the European Pharmacopoeia, current edition.
Closures
Elastomer stoppers - Internal diameter 7 mm. External diameter 13 mm, complying with the European Pharmacopoeia, current edition.
Sealing
Perforated aluminium capsule.
Size
10 x 1 and 50 x 1 doses
Not all pack sizes may be marketed

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate

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

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

Vm 05653/4047

9. DATE OF FIRST AUTHORISATION

Date : 17 October 2005

10. DATE OF REVISION OF THE TEXT

Date : May 2012