

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**  
**Plastic box**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

LETIFEND lyophilisate and solvent for solution for injection

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each dose of 0.5 ml contains:

*Leishmania infantum*, strain MON-1, recombinant protein Q  $\geq$  36.7 EU

**3. PACKAGE SIZE**

1 vial of lyophilisate and 1 vial of solvent (1 dose)

4 vials of lyophilisate and 4 vials of solvent (4 doses)

5 vials of lyophilisate and 5 vials of solvent (5 doses)

10 vials of lyophilisate and 10 vials of solvent (10 doses)

20 vials of lyophilisate and 20 vials of solvent (20 doses)

25 vials of lyophilisate and 25 vials of solvent (25 doses)

50 vials of lyophilisate and 50 vials of solvent (50 doses)

100 vials of lyophilisate and 100 vials of solvent (100 doses)

**4. TARGET SPECIES**

Dogs.

**5. INDICATIONS**

**6. ROUTES OF ADMINISTRATION**

Subcutaneous use.

**7. WITHDRAWAL PERIODS**

**8. EXPIRY DATE**

Exp {mm/yyyy}

Once reconstituted use immediately.

## **9. SPECIAL STORAGE PRECAUTIONS**

Store in a refrigerator.  
Do not freeze.

## **10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”**

Read the package leaflet before use.

## **11. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

For animal treatment only.

## **12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”**

Keep out of the sight and reach of children.

## **13. NAME OF THE MARKETING AUTHORISATION HOLDER**

LETI Pharma, S.L.U.

## **14. MARKETING AUTHORISATION NUMBERS**

Vm 44009/5000

## **15. BATCH NUMBER**

Lot {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING  
UNITS**  
**Vial of lyophilisate**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

LETIFEND lyophilisate



**2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES**

*Leishmania infantum*, strain MON-1, recombinant protein Q

**3. BATCH NUMBER**

Lot {number}

**4. EXPIRY DATE**

Exp {mm/yyyy}

Once reconstituted use immediately.

**5. NAME OF THE MARKETING AUTHORISATION HOLDER**

Company logo (LETI Pharma, S.L.U.)

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING  
UNITS**  
Vial of solvent

**1. NAME OF THE DILUENT/SOLVENT**

LETIFEND solvent



**2. TARGET SPECIES**

**3. BATCH NUMBER**

Lot {number}

**4. EXPIRY DATE**

Exp {mm/yyyy}

**5. NAME OF THE MARKETING AUTHORISATION HOLDER**

Company logo (LETI Pharma, S.L.U.)

## PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

### PACKAGE LEAFLET

#### 1. Name of the veterinary medicinal product

LETIFEND lyophilisate and solvent for solution for injection for dogs

#### 2. Composition

Each dose of 0.5 ml contains:

##### Active substance:

*Leishmania infantum*, strain MON-1, recombinant protein Q:  $\geq 36.7$  ELISA units (EU)\*

\*Antigen content determined in an ELISA against an internal standard.

White lyophilisate.

#### 3. Target species

Dogs.

#### 4. Indications for use

For active immunisation of non-infected dogs from 6 months of age to reduce the risk of developing an active infection and/or clinical disease after exposure to *Leishmania infantum*.

The efficacy of the vaccine was demonstrated in a field study where dogs were naturally exposed to *Leishmania infantum* in zones with high infection pressure over a two-year period.

In laboratory studies including experimental challenge with *Leishmania infantum*, the vaccine reduced the severity of the disease, including clinical signs and parasite burden in spleen and lymph nodes.

Onset of immunity: 4 weeks after vaccination.

Duration of immunity: 1 year after vaccination.

#### 5. Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

## **6. Special warnings**

Vaccinate healthy and non-infected animals only.

The vaccine is safe in infected dogs. Re-vaccination of infected dogs did not worsen the course of the disease (during the 2-month observation period). No efficacy has been demonstrated in these animals.

A test for the detection of *Leishmania* infection is recommended prior to vaccination.

The impact of the vaccine in terms of public health and control of the human infection cannot be estimated from available data.

### Special precautions for safe use in the target species:

De-worming of infested dogs prior to vaccination is recommended.

It is essential that measures to reduce exposure to sand-flies are employed in vaccinated animals.

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

Not applicable.

### Special precautions for the protection of the environment:

Not applicable.

### Pregnancy and lactation:

The safety of the veterinary medicinal product has not been established during pregnancy or lactation. Therefore, the use is not recommended during pregnancy and lactation.

### Interaction with other medicinal products and other forms of interaction:

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:

Following administration of a double dose of the vaccine, no adverse reactions other than those mentioned in section on Adverse events were observed.

### Major incompatibilities:

Do not mix with any other veterinary medicinal product, except solvent supplied for use with the medicinal product.

## 7. Adverse events

Dogs.

|  |   |
|--|---|
| Very common<br>(>1 animal / 10 animals treated):                               | Injection site scratching <sup>1</sup>  |
| Very rare<br>(<1 animal / 10,000 animals treated, including isolated reports): | Hypersensitivity reactions <sup>2</sup> : allergic skin reaction (e.g. allergic oedema -swelling-, urticaria -rash-, allergic pruritus -itching-) or anaphylaxis<br>Lethargy <sup>3</sup> -inactivity-, hyperthermia <sup>3</sup> – fever<br>Vomiting <sup>3</sup> , diarrhoea <sup>3</sup> |

<sup>1</sup> Spontaneous resolution observed within 4 hours.

<sup>2</sup> Appropriate symptomatic treatment should be administered as needed.

<sup>3</sup> Treatment should be administered as needed.

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via the national reporting system:

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: [adverse.events@vmd.gov.uk](mailto:adverse.events@vmd.gov.uk)

## 8. Dosage for each species, routes and method of administration

Subcutaneous use.

Primary vaccination scheme:

A single dose of 0.5 ml to be administered to dogs from 6 months of age.

Re-vaccination scheme:

A single dose of 0.5 ml to be given annually thereafter.

## 9. Advice on correct administration

Reconstitute one vial of the white lyophilisate using 0.5 ml of the solvent. Shake gently to give a clear solution, and administer immediately the entire content (0.5 ml) of the reconstituted product.

## 10. Withdrawal periods

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.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.

Shelf life after reconstitution according to directions: use immediately.

## **12. Special precautions for disposal**

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 applicable national collection systems. These measures should help to protect the environment.

## **13. Classification of veterinary medicinal products**

Veterinary medicinal product subject to prescription.

## **14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES**

Vm 44009/5000

### Pack sizes:

Plastic box containing 1 vial of 1 dose of lyophilisate and 1 vial of 0.8 ml of solvent.

Plastic box containing 4 vials of 1 dose of lyophilisate and 4 vials of 0.8 ml of solvent.

Plastic box containing 5 vials of 1 dose of lyophilisate and 5 vials of 0.8 ml of solvent.

Plastic box containing 10 vials of 1 dose of lyophilisate and 10 vials of 0.8 ml of solvent.

Plastic box containing 20 vials of 1 dose of lyophilisate and 20 vials of 0.8 ml of solvent.

Plastic box containing 25 vials of 1 dose of lyophilisate and 25 vials of 0.8 ml of solvent.

Plastic box containing 50 vials of 1 dose of lyophilisate and 50 vials of 0.8 ml of solvent.

Plastic box containing 100 vials of 1 dose of lyophilisate and 100 vials of 0.8 ml of solvent.

Not all pack sizes may be marketed.

## 15. PID link (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on [www.gov.uk](http://www.gov.uk).

## 16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release:

LETI Pharma, S.L.U.  
C/ Del Sol 5, Polígono Industrial Norte  
Tres Cantos  
28760 Madrid  
Spain

Local representatives and contact details to report suspected adverse reactions:

### United Kingdom (Great Britain)

MSD Animal Health UK Limited  
Walton Manor, Walton,  
Milton Keynes,  
Buckinghamshire, MK7 7AJ (United Kingdom)  
Tel: + 44 (0) 1908 685685

### United Kingdom (Northern Ireland)

INTERVET  
Rue Olivier de Serres, Angers Technopole  
40971 Beaucouze CEDEX (France)  
Tél: + 33 (0) 2 41 22 83 83

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

## 17. Other information

POM-V

To stimulate active immunity against disease caused by *Leishmania infantum* parasites.

Diagnostic tools designed to detect *Leishmania* antibodies (SLA or IFAT or rk-39 rapid diagnostic tests) should be suitable to enable discrimination between dogs vaccinated with this vaccine and dogs infected with *Leishmania infantum*.

The efficacy of the vaccine was demonstrated in a field study where seronegative dogs from a variety of breeds were naturally exposed to *Leishmania infantum* in zones with high infection pressure over a two year period. The data has shown that a

vaccinated dog has 9.8 times less risk to develop clinical signs, 3.5 times less risk of having detectable parasites and 5 times less risk to develop clinical disease than a non-vaccinated dog.

*Gavin Hall*  
Approved: 04 July 2025