

**ANNEX I**

**SUMMARY OF PRODUCT CHARACTERISTICS**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

LETIFEND lyophilisate and solvent for solution for injection for dogs

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 0.5 ml contains:

### Lyophilisate

#### Active substance:

Recombinant Protein Q from *Leishmania infantum* MON-1  $\geq 36.7$  ELISA Units (EU) \*

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

For the full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Lyophilisate and solvent for solution for injection.

White lyophilisate.

## 4. CLINICAL PARTICULARS

### 4.1 Target species

Dogs.

### 4.2 Indications for use, specifying the target species

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 years 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.

### 4.3 Contraindications

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

### 4.4 Special warnings for each target species

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.

#### **4.5 Special precautions for use**

##### Special precautions for use in animals

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

None.

#### **4.6 Adverse reactions (frequency and seriousness)**

After vaccination, scratching at the injection site has been observed very commonly in dogs.

Spontaneous resolution of such reaction was observed within 4 hours.

Hypersensitivity reactions (e.g. anaphylaxis, skin manifestations such as oedema, urticaria, pruritus) have been reported in very rare cases. In case of such an allergic or anaphylactic reaction, appropriate symptomatic treatment should be administered.

Lethargy, vomiting, diarrhoea and hyperthermia following vaccination have each been reported to occur very rarely based on post-marketing safety experience. Treatment should be administered as needed.

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)

#### **4.7 Use during pregnancy, lactation or lay**

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.

#### **4.8 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.

#### **4.9 Amounts to be administered and administration route**

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.

##### Method of administration:

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

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

Following administration of a double dose of the vaccine, no adverse reactions other than those mentioned in section 4.6 were observed.

#### **4.11 Withdrawal period(s)**

Not applicable.

### **5. IMMUNOLOGICAL PROPERTIES**

Pharmacotherapeutic group: Immunologicals for Canidae – dog – inactivated parasitic vaccines – leishmania.

ATCvet code: QI07AO01

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.

### **6. PHARMACEUTICAL PARTICULARS**

#### **6.1 List of excipients**

Lyophilisate:

Sodium chloride

Arginine hydrochloride

Boric acid.

Solvent:

Water for injections.

#### **6.2 Major incompatibilities**

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

#### **6.3 Shelf life**

Lyophilisate:

Shelf life of the veterinary medicinal product as packaged for sale: 4 years.

Solvent:

Shelf life of the solvent: 5 years.

Shelf life after reconstitution according to directions: use immediately.

#### **6.4. Special precautions for storage**

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

Do not freeze.

#### **6.5 Nature and composition of immediate packaging**

##### Lyophilisate vial

Type I glass vials containing 1 dose of vaccine.

##### Solvent vial

Type I glass vials containing 0.8 ml of solvent.

Vials are both closed with a bromobutyl stopper and an aluminium cap.

##### 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.

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

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

### **7. MARKETING AUTHORISATION HOLDER**

LETI Pharma, S.L.U.  
C/ Del Sol 5,  
Polígono Industrial Norte  
Tres Cantos  
28760 Madrid  
SPAIN  
+34 91 771 17 90

### **8. MARKETING AUTHORISATION NUMBER(S)**

EU/2/16/195/001-008

### **9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 20/04/2016

Date of last renewal: 09/02/2021

## **10 DATE OF REVISION OF THE TEXT**

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (<http://www.ema.europa.eu/>).

## **PROHIBITION OF SALE, SUPPLY AND/OR USE**

Any person intending to manufacture, import, possess, sell, supply and use this veterinary medicinal product must first consult the relevant Member State's competent authority on the current vaccination policies, as these activities may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation.

## **ANNEX II**

- A. MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCE AND  
MANUFACTURER RESPONSIBLE FOR BATCH RELEASE**
- B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE**
- C. STATEMENT OF THE MRLs**

**A. MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCE AND  
MANUFACTURER RESPONSIBLE FOR BATCH RELEASE**

Name and address of the manufacturer of the biological active substance

3P Biopharmaceuticals, S.L.  
C/ Mocholi 2, Poligono Industrial Mocholi,  
Noain, 31110 Navarra  
SPAIN

Name and address of the manufacturer responsible for batch release:

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

**B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE**

Veterinary medicinal product subject to prescription.

**C. STATEMENT OF THE MRLs**

Not applicable.



**ANNEX III**  
**LABELLING AND PACKAGE LEAFLET**

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**Plastic box**

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

LETIFEND lyophilisate and solvent for solution for injection for dogs.

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each dose of 0.5 ml:

Recombinant Protein Q from *Leishmania infantum* MON-1  $\geq 36.7$  EU

**3. PHARMACEUTICAL FORM**

Lyophilisate and solvent for solution for injection.

**4. 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)

**5. TARGET SPECIES**

Dogs.

**6. INDICATION(S)****7. METHOD AND ROUTE(S) OF ADMINISTRATION**

Subcutaneous use.

Read the package leaflet before use.

**8. WITHDRAWAL PERIOD(S)****9. SPECIAL WARNING(S), IF NECESSARY**

**10. EXPIRY DATE**

EXP {mm/yyyy}

Once reconstituted use immediately.

**11. SPECIAL STORAGE CONDITIONS**

Store in a refrigerator.

Do not freeze.

**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. 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**

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

**16. MARKETING AUTHORISATION NUMBER(S)**

EU/2/16/195/001	1 dose
EU/2/16/195/002	4 doses
EU/2/16/195/003	5 doses
EU/2/16/195/004	10 doses
EU/2/16/195/005	20 doses
EU/2/16/195/006	25 doses
EU/2/16/195/007	50 doses
EU/2/16/195/008	100 doses

**17. MANUFACTURER'S 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 for dogs



**2. QUANTITY OF THE ACTIVE SUBSTANCE(S)**

Recombinant Protein Q from *L. infantum* MON-1

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

1 dose

**4. ROUTE(S) OF ADMINISTRATION**

SC

**5. WITHDRAWAL PERIOD(S)**

**6. BATCH NUMBER**

Lot {number}

**7. EXPIRY DATE**

EXP {mm/yyyy}

**8. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

For animal treatment only.

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

**Vial of solvent**

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

LETIFEND solvent for dogs



**2. QUANTITY OF THE ACTIVE SUBSTANCE(S)**

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

0.8 ml

**4. ROUTE(S) OF ADMINISTRATION**

**5. WITHDRAWAL PERIOD(S)**

**6. BATCH NUMBER**

Lot {number}

**7. EXPIRY DATE**

EXP {mm/yyyy}

**8. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

For animal treatment only

## **B. PACKAGE LEAFLET**

**PACKAGE LEAFLET:**  
**LETIFEND lyophilisate and solvent for solution for injection for dogs**

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

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

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

LETIFEND lyophilisate and solvent for solution for injection for dogs

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

Each dose of 0.5 ml contains:

**Lyophilisate** (white lyophilisate)

Active substance:

Recombinant Protein Q from *Leishmania infantum* MON-1:  $\geq 36.7$  ELISA units (EU) \*

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

Excipients:

Sodium chloride  
Arginine hydrochloride  
Boric acid.

**Solvent**

Water for injections: q.s. 0.5 ml.

**4. INDICATION(S)**

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 years 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. ADVERSE REACTIONS**

After vaccination, scratching at the injection site has been observed very commonly in dogs.

Spontaneous resolution of such reaction was observed within 4 hours.

Hypersensitivity reactions (e.g. anaphylaxis, skin manifestations such as oedema, urticaria, pruritus) have been reported in very rare cases. In case of such an allergic or anaphylactic reaction, appropriate symptomatic treatment should be administered.

Lethargy, vomiting, diarrhoea and hyperthermia following vaccination have each been reported to occur very rarely based on post-marketing safety experience. Treatment should be administered as needed.

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.

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 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.

Shelf life after reconstitution according to directions: use immediately  
Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP.

## **12. SPECIAL WARNING(S)**

### Special warnings for each target species:

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 use in animals:

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:

None.

### 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 (symptoms, emergency procedures, antidotes):

Following administration of a double dose of the vaccine, no adverse reactions other than those mentioned in section 6 were observed.

### Incompatibilities:

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

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

Medicines should not be disposed of via wastewater or household waste.

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

#### **14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED**

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (<http://www.ema.europa.eu/>).

#### **15. OTHER INFORMATION**

##### Lyophilisate vial

Type I glass vials containing 1 dose of vaccine.

##### Solvent vial

Type I glass vials containing 0.8 ml of solvent.

Vials are both closed with a bromobutyl stopper and an aluminium cap.

##### 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.

Any person intending to manufacture, import, possess, sell, supply and use this veterinary medicinal product must first consult the relevant Member State's competent authority on the current vaccination policies, as these activities may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation.

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

##### **België/Belgique/Belgien**

LETI Pharma, S.L.U.  
C/ Del Sol 5, Polígono Industrial Norte  
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##### **Lietuva**

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##### **Република България**

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##### **Luxembourg/Luxemburg**

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Tél/Tel: + 34 91 771 17 90

##### **Česká republika**

LETI Pharma, S.L.U.  
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##### **Magyarország**

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**Danmark**

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**Deutschland**

Intervet Deutschland GmbH  
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D-85716 Unterschleißheim (DEUTSCHLAND)

**Eesti**

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**Ελλάδα**

Intervet Hellas AE  
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**España**

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**France**

INTERVET  
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40971 Beaucouze CEDEX (FRANCE)  
Tél: + 33 (0) 2 41 22 83 83

**Hrvatska**

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Tres Cantos 28760 Madrid (ŠPANJOLSKA)  
Tel: + 34 91 771 17 90

**Ireland**

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**Ísland**

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**Malta**

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**Nederland**

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**Norge**

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**România**

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Tres Cantos 28760 Madrid (SPANIA)  
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**Slovenija**

LETI Pharma, S.L.U.  
C/ Del Sol 5, Polígono Industrial Norte  
Tres Cantos 28760 Madrid (ŠPANIJA)  
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**Slovenská republika**

LETI Pharma, S.L.U.  
C/ Del Sol 5, Polígono Industrial Norte  
Tres Cantos 28760 Madrid (ŠPANIELSKO)  
Tel: + 34 91 771 17 90

**Italia**

MSD Animal Health S.r.l.  
Strada di Olgia Vecchia snc, Centro Direzionale  
Milano Due, Palazzo Canova  
20054 Segrate (MI) (ITALIA)  
Tel: + 39 02 516861

**Κύπρος**

Intervet Hellas AE  
Αγίου Δημητρίου 63,  
174 56 Άλμιος, Αττική (ΕΛΛΑΔΑ)  
Τηλ: +30 210 9897430

**Latvija**

LETI Pharma, S.L.U.  
C/ Del Sol 5, Polígono Industrial Norte  
Tres Cantos 28760 Madride (SPĀNIJA)  
Tel: + 34 91 771 17 90

**Suomi/Finland**

LETI Pharma, S.L.U.  
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Puh/Tel: + 34 91 771 17 90

**Sverige**

LETI Pharma, S.L.U.  
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**United Kingdom (Northern Ireland)**

INTERVET  
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Tél: + 33 (0) 2 41 22 83 83