ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CaniLeish lyophilisate and solvent for suspension for injection for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 1 ml vaccine contains:

Lyophilisate:

Active substances:
Leishmania infantum Excreted Secreted Proteins (ESP) at least 100 µg
Adjuvant:
Purified extract of *Quillaja saponaria* (QA-21): 60 µg

Solvent:
Sodium chloride solution 9 mg/ml (0.9%) 1 ml

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for injection.
Lyophilisate: beige freeze-dried fraction
Solvent: colourless liquid

4. CLINICAL PARTICULARS

4.1 Target species

Dogs.

4.2 Indications for use, specifying the target species

For the active immunization of Leishmania negative dogs from 6 months of age to reduce the risk to develop an active infection and clinical disease after contact with *Leishmania infantum*.
The efficacy of the vaccine has been demonstrated in dogs submitted to multiple natural parasite exposure in zones with high infection pressure.

Onset of immunity: 4 weeks after the primary vaccination course.

Duration of immunity: 1 year after the last (re-)vaccination.

4.3 Contraindications

Do not use in case of hypersensitivity to the active substance, to the adjuvant or to any of the excipients.

4.4 Special warnings for each target species

Transient antibodies against Leishmania detected by immunofluorescence antibody test (IFAT) may appear after vaccination. Antibodies due to vaccination can be differentiated from antibodies due to natural infection by using a rapid diagnostic serological test as a first step to a differential diagnosis.

In areas of low or no infection pressure a benefit/risk assessment must be undertaken by the veterinarian before deciding to use the vaccine in dogs.

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

Vaccinate only healthy animals. The efficacy of vaccination in dogs already infected has not been investigated and therefore cannot be recommended. In dogs developing a leishmaniosis (active infection and/or disease) despite vaccination, proceeding with vaccine injections showed no benefit. Injection of the vaccine to dogs already infected by *Leishmania infantum* did not show any specific adverse reactions other than those described in section 4.6. The detection of Leishmania infection using a rapid serological diagnostic test is recommended prior to vaccination.

In case of anaphylactic reaction appropriate symptomatic treatment should be administered and clinical monitoring should be maintained until symptoms resolve. In order to facilitate the quick implementation of such treatment, should an anaphylactic reaction occur, an observation of the dog by the owner during the hours following vaccination is recommended.

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

Vaccination should not prevent other measures taken to reduce exposure to sandflies.

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

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

4.6 Adverse reactions (frequency and seriousness)

After injection, moderate and transient local reactions such as swelling, nodule, pain on palpation or erythema are common, but those reactions resolve spontaneously within 2 to 15 days. In very rare cases a more severe reaction at the injection site (injection site necrosis, vasculitis) has been reported.

Other transient signs seen following vaccination such as hyperthermia, apathy and digestive disorders lasting 1 to 6 days are common. In rare cases anorexia and emesis have been reported.

Allergic-type reactions are rare. In very rare cases, serious hypersensitivity reactions have been observed which could be fatal. A symptomatic treatment should be rapidly implemented and clinical monitoring should be maintained until symptoms resolve.

The frequency of adverse reactions is defined using the following convention:

- Very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment),
- Common (more than 1 but less than 10 animals in 100 animals),
- Uncommon (more than 1 but less than 10 animals in 1,000 animals),
- Rare (more than 1 but less than 10 animals in 10,000 animals),
- Very rare (less than 1 animal in 10,000 animals, including isolated reports).

4.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy and 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.

After reconstitution of the lyophilisate with the solvent, shake gently and administer immediately one dose of 1 ml subcutaneously according to the following vaccination schedule:
Primary vaccination course:

- First dose from 6 months of age,
- Second dose 3 weeks later,
- Third dose 3 weeks after the 2nd injection.

Annual re-vaccination:

- One booster injection of a single dose should be given 1 year after the third injection and annually thereafter.

The appearance of the reconstituted product is reddish-brown.

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

No adverse reactions other than those mentioned in section 4.6 were observed after the administration of a double-dose of the vaccine.

4.11 Withdrawal period

Not applicable.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for canidae – dog – inactivated parasitic vaccine.
ATC vet code : QI07AO01.

Vaccination induces a cell-mediated immunity evidenced by:

- the appearance of specific IgG2 antibodies to *Leishmania infantum* excreted secreted proteins,
- an enhancement of the leishmanicidal activity of the macrophages,
- a T-cell lymphoproliferation with the secretion of interferon gamma cytokine,
- a positive T-cell-mediated immune response, directed against the Leishmanian antigen (skin test).

Efficacy data have shown that a vaccinated dog has 3.6 times less risk to develop an active infection and 4 times less risk to develop a clinical disease than a non-vaccinated dog, on dogs submitted to multiple natural parasite exposure in zones with high infection pressure.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lyophilisate
Purified extract of *Quillaja saponaria* (QA-21)
Trometamol
Sucrose
Mannitol

Solvent
Sodium chloride
Water for injections

6.2 Incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: use immediately after reconstitution.

6.4. Special precautions for storage

Store and transport refrigerated (2°C – 8°C).
Protect from light.

6.5 Nature and composition of immediate packaging

Type I glass vial containing 1 dose of lyophilisate and type I glass vial containing 1 ml of solvent, both closed with a butyl elastomer closure and sealed with an aluminium cap.

Pack sizes:
Plastic box containing 1 vial of 1 dose of lyophilisate and 1 vial of 1 ml of solvent.
Plastic box containing 1 vial of 1 dose of lyophilisate, 1 vial of 1 ml of solvent, 1 syringe and 1 needle.
Plastic box containing 3 vials of 1 dose of lyophilisate and 3 vials of 1 ml of solvent.
Plastic box containing 5 vials of 1 dose of lyophilisate and 5 vials of 1 ml of solvent.
Plastic box containing 10 vials of 1 dose of lyophilisate and 10 vials of 1 ml of solvent.
Plastic box containing 15 vials of 1 dose of lyophilisate and 15 vials of 1 ml of solvent.
Plastic box containing 25 vials of 1 dose of lyophilisate and 25 vials of 1 ml of solvent.
Plastic box containing 30 vials of 1 dose of lyophilisate and 30 vials of 1 ml of solvent.
Plastic box containing 50 vials of 1 dose of lyophilisate and 50 vials of 1 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

VIRBAC
1ère avenue – 2065 m – LID
06516 Carros
France
Tel. 0033/4.92.08.73.00
Fax. 0033/4.92.08.73.48
E-mail. darprocedure@virbac.com

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/11/121/001-009

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

14/03/2011

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

The import, sale, supply and/or use of CaniLeish is or may be prohibited in certain Member States on the whole or part of their territory pursuant to national animal health policy. Any person intending to import, sell, supply and/or use CaniLeish must consult the relevant Member State's competent authority on the current vaccination policies prior to the import, sale, supply and/or use.

ANNEX II

A. MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCE AND MANUFACTURING AUTHORISATION HOLDER 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 MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer of the biological active substance

VIRBAC
1ère avenue – 2065 m – L.I.D.
06516 Carros
France

Name and address of the manufacturer responsible for batch release

VIRBAC
1ère avenue – 2065 m – L.I.D.
06516 Carros
France

B. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION REGARDING SUPPLY OR USE

To be supplied only on veterinary prescription.

According to Article 71 of Directive 2001/82/EC of the European Parliament and of the Council as amended, Member States prohibit or may prohibit the import, sale, supply and/or use of the veterinary medicinal product on the whole or part of their territory if it is established that:

a) the administration of the veterinary medicinal product to animals will interfere with the implementation of national programmes for the diagnosis, control and eradication of animal diseases, or will cause difficulties in certifying the absence of contamination in live animals or in foodstuffs or other products obtained from treated animals.

b) the disease to which the veterinary medicinal product is intended to confer immunity is largely absent from the territory.

C. STATEMENT OF THE MRLs

Not applicable.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box of 1 vial of lyophilisate and 1 vial of solvent
Box of 1 vial of lyophilisate, 1 vial of solvent, 1 syringe and 1 needle.
Box of 3 vials of lyophilisate and 3 vials of solvent
Box of 5 vials of lyophilisate and 5 vials of solvent

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CaniLeish lyophilisate and solvent for suspension for injection for dogs

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

L. infantum Proteins (ESP) ≥ 100 µg

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for injection.

4. PACKAGE SIZE

1 dose.
3 doses.
5 doses.

5. TARGET SPECIES

Dogs.

6. INDICATION

7. METHOD AND ROUTE OF ADMINISTRATION

Subcutaneous use.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP: {month/year}
Use immediately after reconstitution.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated.
Protect from light.

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

Read the 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. To be supplied on veterinary subscription.

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
France

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/11/121/001
EU/2/11/121/002
EU/2/11/121/003
EU/2/11/121/004

17. MANUFACTURER'S BATCH NUMBER

Batch: {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box of 10 vials of lyophilisate and 10 vials of solvent
Box of 15 vials of lyophilisate and 15 vials of solvent
Box of 25 vials of lyophilisate and 25 vials of solvent
Box of 30 vials of lyophilisate and 30 vials of solvent
Box of 50 vials of lyophilisate and 50 vials of solvent

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CaniLeish lyophilisate and solvent for suspension for injection for dogs

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each dose of 1 ml vaccine contains:
L. infantum Proteins (ESP) ≥ 100 µg

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for injection.

4. PACKAGE SIZE

10 doses.
15 doses.
25 doses.
30 doses.
50 doses.

5. TARGET SPECIES

Dogs.

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous use.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP: {month/year}
Use immediately after reconstitution.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated.
Protect from light.

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

Read the 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. 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

VIRBAC
1ère avenue – 2065 m – L.I.D.
06516 Carros
France

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/11/121/005
EU/2/11/121/006
EU/2/11/121/007
EU/2/11/121/008
EU/2/11/121/009

17. MANUFACTURER'S BATCH NUMBER

Batch: {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial with 1 dose of lyophilisate

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CaniLeish lyophilisate

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

L. infantum ESP ≥ 100 µg

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

1 dose

4. ROUTE(S) OF ADMINISTRATION

SC

5. WITHDRAWAL PERIOD

6. BATCH NUMBER

Batch: {number}

7. EXPIRY DATE

EXP: {month/year}
Use immediately after reconstitution.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial with 1 dose of solvent

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CaniLeish solvent

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Sodium chloride 9 mg/ml (0.9%)

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

1 ml

4. ROUTE(S) OF ADMINISTRATION

5. WITHDRAWAL PERIOD

Not applicable.

6. BATCH NUMBER

Batch: {number}

7. EXPIRY DATE

EXP: {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

CaniLeish lyophilisate and solvent for suspension 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:

VIRBAC
1ère avenue – 2065 m – L.I.D.
06516 Carros
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

CaniLeish lyophilisate and solvent for suspension for injection for dogs

3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS

Each dose of 1 ml vaccine contains:

Lyophilisate:

Active substance:
Leishmania infantum Excreted Secreted Proteins (ESP) at least 100 µg
Adjuvant:
Purified extract of *Quillaja saponaria* (QA-21) 60 µg

Solvent:
Sodium chloride solution 9 mg/ml (0.9%) 1 ml

4. INDICATIONS

For the active immunization of Leishmania negative dogs from 6 months of age to reduce the risk to develop an active infection and clinical disease after contact with *Leishmania infantum*.
The efficacy of the vaccine has been demonstrated in dogs submitted to multiple natural parasite exposure in zones with high infection pressure.

Onset of immunity: 4 weeks after the primary vaccination course.

Duration of immunity: 1 year after the last (re-)vaccination.

5. CONTRAINDICATIONS

Do not use in case of hypersensitivity to the active substance, to the adjuvant or to any of the excipients.

6. ADVERSE REACTIONS

After injection, moderate and transient local reactions such as swelling, nodule, pain on palpation or erythema are common, but these reactions resolve spontaneously within 2 to 15 days. In very rare cases a more severe reaction at the injection site (injection site necrosis, vasculitis) has been reported.

Other transient signs seen following vaccination such as hyperthermia, apathy and digestive disorders lasting 1 to 6 days are common. In rare cases anorexia and emesis have been reported.

Allergic-type reactions are rare. In very rare cases, serious hypersensitivity reactions have been observed which could be fatal. A symptomatic treatment should be rapidly implemented and clinical monitoring should be maintained until symptoms resolve.

The frequency of adverse reactions is defined using the following convention:
- Very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment),
- Common (more than 1 but less than 10 animals in 100 animals),
- Uncommon (more than 1 but less than 10 animals in 1,000 animals),
- Rare (more than 1 but less than 10 animals in 10,000 animals),
- Very rare (less than 1 animal in 10,000 animals, including isolated reports).

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs.

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

Subcutaneous use.

Primary vaccination course:
- First dose from 6 months of age,
- Second dose 3 weeks later,
- Third dose 3 weeks after the 2nd injection.

Annual re-vaccination:
- One booster injection of a single dose should be given 1 year after the third injection and annually thereafter.

9. ADVICE ON CORRECT ADMINISTRATION

After reconstitution of the lyophilisate with the solvent, shake gently and administer immediately one dose of 1 ml subcutaneously according to the vaccination schedule.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store and transport refrigerated (2 °C – 8 °C).
Protect from light.

12. SPECIAL WARNINGS

Special precautions for use in animals

Vaccinate only healthy animals. The efficacy of vaccination in dogs already infected has not been investigated and therefore cannot be recommended. In dogs developing a leishmaniosis (active infection and/or disease) despite vaccination, proceeding with vaccine injections showed no benefit. Injection of the vaccine to dogs already infected by *Leishmania infantum* did not show any specific adverse reactions other than those described in section 6. The detection of Leishmania infection using a rapid serological diagnostic test is recommended prior to vaccination.

In case of anaphylactic reaction appropriate symptomatic treatment should be administered and clinical monitoring should be maintained until symptoms resolve. In order to facilitate the quick implementation of such treatment, should an anaphylactic reaction occur, an observation of the dog by the owner during the hours following vaccination is recommended.

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

Vaccination should not prevent other measures taken to reduce exposure to sandflies.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

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

Interactions with other medicinal products
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.

Incompatibilities
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

Overdose
No adverse reactions other than those mentioned in section 6 were observed after the administration of a double-dose of the vaccine.

Other information
Transient antibodies against Leishmania detected by immunofluorescence antibody test (IFAT) may appear after vaccination. Antibodies due to vaccination can be differentiated from antibodies due to natural infection by using a rapid diagnostic serological test as a first step to a differential diagnosis.
In areas of low or no infection pressure a benefit/risk assessment must be undertaken by the veterinarian before deciding to use the vaccine in dogs.

The impact of the vaccine in terms of public health and control of the human infection cannot be estimated from available data.
Efficacy data have shown that a vaccinated dog has 3.6 times less risk to develop an active infection and 4 times less risk to develop a clinical disease than a non-vaccinated dog, on dogs submitted to multiple natural parasite exposure in zones with high infection pressure.

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 how to dispose of medicines no longer required.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

Detailed information on this product is available on the website of the European Medicines Agency http://www.ema.europa.eu/.

15. OTHER INFORMATION

Type I glass vial containing 1 dose of lyophilisate and type I glass vial containing 1 ml of solvent, both closed with a butyl elastomer closure and sealed with an aluminium cap.

Pack sizes:
Plastic box containing 1 vial of 1 dose of lyophilisate and 1 vial of 1 ml of solvent.
Plastic box containing 1 vial of 1 dose of lyophilisate, 1 vial of 1 ml of solvent, 1 syringe and 1 needle.
Plastic box containing 3 vials of 1 dose of lyophilisate and 3 vials of 1 ml of solvent.
Plastic box containing 5 vials of 1 dose of lyophilisate and 5 vials of 1 ml of solvent.
Plastic box containing 10 vials of 1 dose of lyophilisate and 10 vials of 1 ml of solvent.
Plastic box containing 15 vials of 1 dose of lyophilisate and 15 vials of 1 ml of solvent.
Plastic box containing 25 vials of 1 dose of lyophilisate and 25 vials of 1 ml of solvent.
Plastic box containing 30 vials of 1 dose of lyophilisate and 30 vials of 1 ml of solvent.
Plastic box containing 50 vials of 1 dose of lyophilisate and 50 vials of 1 ml of solvent.

Not all pack sizes may be marketed.

The import, sale, supply and/or use of CaniLeish is or may be prohibited in certain Member States on the whole or part of their territory pursuant to national animal health policy. Any person intending to import, sell, supply and/or use CaniLeish must consult the relevant Member State's competent authority on the current vaccination policies prior to the import, sale, supply and/or use.

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

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Česká republika
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Danmark
VIRBAC Danmark A/S
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