ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

NEOLEISH nasal spray solution for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:

Each 1 mL dose contains:

pPAL-LACK supercoiled plasmid DNA coding for LACK protein
from *Leishmania infantum* ..... 212.5-250 µg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Nasal spray, solution.

Colourless, transparent solution.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs.

4.2 Indications for use, specifying the target species

For the active immunisation of Leishmania negative dogs from 6 months of age to reduce the risk to develop 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 bone marrow, spleen and lymph nodes.

Onset of immunity: 58 days after the primary vaccination course.

Duration of immunity: 6 months after the primary vaccination course.

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 animals only.

The detection of Leishmania infection using a suitable diagnostic test is recommended prior to vaccination.

No information is available on the use of the vaccine in animals with antibodies against Leishmania, including those with maternal antibodies.

The impact of the vaccine in terms of public health and control of 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.

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

Personal protective equipment consisting of gloves, a surgical mask and safety glasses should be worn when handling the veterinary medicinal product and during the vaccination procedure.

After each use, disinfect hands and vaccination area using an appropriate disinfectant.

Wash hands and rinse mucosal surfaces with water if contamination occurs.

Other precautions

Vaccinated dogs may excrete the vaccine up to 15 days following vaccination. Avoid accidental contact with faeces during this period.

4.6 Adverse reactions (frequency and seriousness)

No local or systemic adverse reactions have been observed after the administration of one dose and repeated administration of a single dose (up to 3 repeated doses).

4.7 Use during pregnancy, lactation or lay

Pregnancy:

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

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.

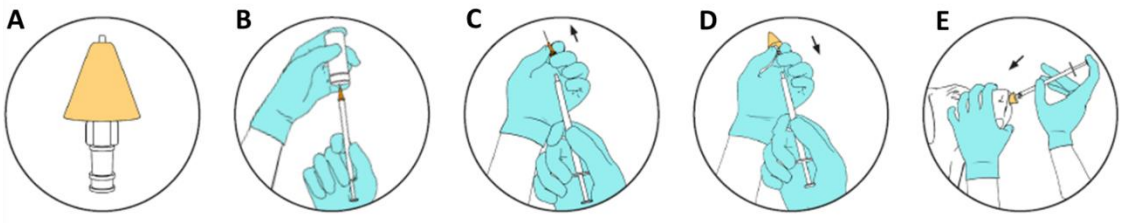
4.9 Amounts to be administered and administration route

Nasal use.
Administer one dose of 1 mL (0.5 mL/nostril) according to the following vaccination schedule:

Primary vaccination:
- First dose from 6 months of age.
- Second dose 2 weeks later.

Revaccination:
- A single dose of the vaccine to be given every 6 months after the primary vaccination course.

Administer the vaccine according to the following steps:



A. Use a commercial device suitable for intranasal administration of veterinary medicinal products adaptable to 1 ml volume injection syringe.

B. Extract the proper volume of vaccine (1 mL) with a needle attached to a syringe.

C. Remove the needle.

D. Attach the commercially intranasal device.

E. With the free hand, hold the dog snout upwards and place snugly the tip of the device against the nostril aiming slightly up and outward to ensure the vaccine is completely delivered into the nose. Then, briskly compress the syringe plunger to deliver half of the medication into the nostril (0.5 mL). Move the device to the opposite nostril and repeat the application process, administering the remaining volume (0.5 mL).

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

A transient increase of the temperature (1.3 ºC) is observed for 4 hours after the administration of ten standard doses of the vaccine followed by the administration of a second dose of the vaccine.

4.11 Withdrawal period(s)

Not applicable.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for Canidae–dog–other immunologicals.
ATC vet code: QI07AX.

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

Vaccination induces an active immune response against Leishmania LACK antigen characterized by specific activation of T-cells in peripheral blood, lymph nodes and spleen, which is associated to specific interferon-gamma release.

Diagnostic tools designed to detect antibodies against *Leishmania infantum* (IFAT 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 dogs 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 approximately 2 times less risk to develop active infection, 3 times less risk to develop clinical disease, 3.5 times less risk of having detectable parasites in blood, than non-vaccinated dogs.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Potassium dihydrogen phosphate
Disodium phosphate anhydrous
Sodium chloride
Water for injections

6.2 Major incompatibilities

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

6.3 Shelf life

Frozen vial
Shelf life of the veterinary medicinal product as packaged for sale: 24 months at -15 ºC - -30ºC.

Thawed vial
1 month at 2ºC – 8ºC within the 24 months shelf life.

Once thawed, the vaccine should not be re-frozen.

6.4. Special precautions for storage

Store and transport frozen (< -15 ºC)
Once thawed, store and transport refrigerated (2 °C – 8 °C).
Protect from light.

6.5 Nature and composition of immediate packaging

Cardboard box with 1 type I glass vial containing 1 dose of 1 mL, with a butyl rubber stopper and aluminium seal.

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 product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

CZ Vaccines S.A.U.
A Relva s/n – Torneiros
36410 O Porriño
Pontevedra
Spain

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/22/290

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation:

10 DATE OF REVISION OF THE TEXT

{DD/MM/YYYY}

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

CZ Vaccines S.A.U.
A Relva s/n – Torneiros
36410 O Porriño
Pontevedra
Spain

Name and address of the manufacturer responsible for batch release

CZ Vaccines S.A.U.
A Relva s/n – Torneiros
36410 O Porriño
Pontevedra
Spain

The printed package leaflet of the medicinal product must state the name and address of the manufacturer responsible for the release of the concerned batch.

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

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

NEOLEISH nasal spray solution for dogs
pPAL-LACK supercoiled plasmid DNA coding for LACK protein from *Leishmania infantum*

2. STATEMENT OF ACTIVE SUBSTANCES

Each 1 mL dose contains:

pPAL-LACK supercoiled plasmid DNA coding for LACK protein
from *Leishmania infantum* ..... 212.5-250 µg

3. PHARMACEUTICAL FORM

Nasal spray, solution

4. PACKAGE SIZE

1 mL

5. TARGET SPECIES

Dogs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Nasal use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Store and transport frozen (< -15 ºC).

Once thawed, store and transport refrigerated (2 °C – 8 °C) for a maximum period of 1 month within the 24-month validity period.

Once thawed, the vaccine should not be re-frozen.

Protect from light.

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

Dispose of waste material in accordance with local requirements.

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

CZ Vaccines S.A.U.
36410 O Porriño – Spain

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/22/290

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Type I glass vial (1 dose)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

NEOLEISH nasal spray solution for dogs
pPAL-LACK supercoiled plasmid DNA coding for LACK protein from *Leishmania infantum*

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each 1 mL dose contains:

pPAL-LACK supercoiled plasmid DNA coding for LACK protein
from *Leishmania infantum* ..... 212.5-250 µg

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

1 mL

4. ROUTE(S) OF ADMINISTRATION

Nasal use

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

NEOLEISH nasal spray solution 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:

CZ Vaccines S.A.U.
A Relva s/n – Torneiros
36410 O Porriño
Pontevedra
Spain

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

NEOLEISH nasal spray, solution for dogs
pPAL-LACK supercoiled plasmid DNA coding for LACK protein from *Leishmania infantum*

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

Active substance:

Each 1 mL dose contains:

pPAL-LACK supercoiled plasmid DNA coding for LACK protein
from *Leishmania infantum* ..... 212.5-250 µg

Colourless, transparent solution.

4. INDICATION(S)

For the active immunization of Leishmania negative dogs from 6 months of age to reduce the risk to develop 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 bone marrow, spleen and lymph nodes.

Onset of immunity: 58 days after the primary vaccination course.

Duration of immunity: 6 months after the primary vaccination course.

5. CONTRAINDICATIONS

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

6. ADVERSE REACTIONS

None.

7. TARGET SPECIES

Dogs

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

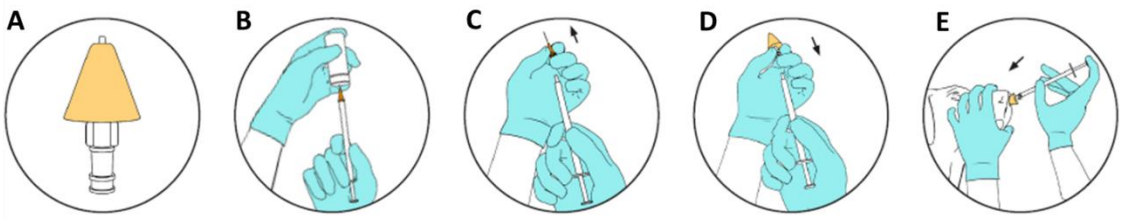
Nasal use.

Administer one dose of 1 mL (0.5 mL/nostril) according to the following vaccination schedule:

Primary vaccination:
- First dose from 6 months of age,
- Second dose 2 weeks later.

Revaccination:
- A single dose of the vaccine to be given every 6 months after the primary vaccination course.

Administer the vaccine according to the following steps:



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B. Extract the proper volume of vaccine (1 mL) with a needle attached to a syringe.

C. Remove the needle.

D. Attach the commercially intranasal device.

E. With the free hand, hold the dog snout upwards and place snugly the tip of the device against the nostril aiming slightly up and outward to ensure the vaccine is completely delivered into the nose. Then, briskly compress the syringe plunger to deliver half of the medication into the nostril (0.5 mL). Move the device to the opposite nostril and repeat the application process, administering the remaining volume (0.5 mL).

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD

Not applicable

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Frozen vial
Store and transport frozen (< -15 ºC)

Thawed vial
Store and transport refrigerated (2 °C – 8 °C) for a maximum period of 1 month within the 24-month validity period.

Once thawed, the vaccine should not be re-frozen.

Protect from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton and the bottle after EXP.

12. SPECIAL WARNINGS

Special warnings for each target species:

No local or systemic adverse reactions have been observed after the administration of one dose and repeated administration of a single dose (up to 3 repeated doses).

Vaccinate healthy animals only.

The detection of Leishmania infection using a suitable diagnostic test is recommended prior to vaccination.

No information is available on the use of the vaccine in animals with antibodies against Leishmania, including those with maternal antibodies.

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

Special precautions for use in animals:

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:

Personal protective equipment consisting of gloves, a surgical mask and safety glasses should be worn when handling the veterinary medicinal product and during the vaccination procedure.

Vaccinated dogs may excrete the vaccine up to 15 days following vaccination. Avoid accidental contact with faeces during this period.

After each use, disinfect hands and vaccination area using an appropriate disinfectant.

Wash hands and rinse mucosal surfaces with water if contamination occurs.

Pregnancy:

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

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):

A transient increase of the temperature (1.3 ºC) is observed for 4 hours after the administration of ten standard doses of the vaccine followed by the administration of a second dose of the vaccine.

Incompatibilities:

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

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. 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

Pack size:
Cardboard box with 1 type I glass vial containing 1 dose of 1 mL, with butyl rubber stopper and aluminium seal.

For animal treatment only.

To be supplied only on veterinary prescription.

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

España

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España
Tel: +34 986330400

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