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 mcg

Excipients:

Qualitative composition of excipients and other constituents
Potassium dihydrogen phosphate
Disodium phosphate anhydrous
Sodium chloride
Water for injections

Colourless, transparent solution.

3. CLINICAL INFORMATION

3.1 Target species

Dogs

3.2 Indications for use for each 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.

3.3 Contraindications

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

3.4 Special warnings

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.

3.5 Special precautions for use

Special precautions for safe use in the target species:
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.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Dogs
None.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

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

3.8 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.

3.9 Administration routes and dosage

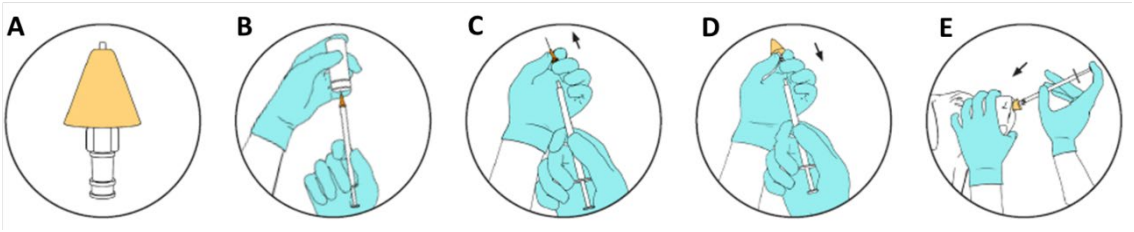
Nasal use.

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 medicinal product 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).

3.10 Symptoms of overdose (and where applicable, emergency procedures and 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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet 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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Frozen vial:
Shelf life of the veterinary medicinal product as packaged for sale: 2 years at -15 ºC to -30 ºC.

Thawed vial:
1 month at 2 ºC – 8 ºC within the 2 years shelf life.

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

5.3 Special precautions for storage

Store and transport frozen { -15 ºC to -30 ºC}.
Once thawed, store and transport refrigerated (2 °C – 8 °C).
Protect from light.

5.4 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.

Cardboard box with 10 type I glass vials containing 1 dose of 1 mL, with a butyl rubber stopper and aluminium seal.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

CZ Vaccines S.A.U.

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/22/290/001-002

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 20/12/2022.

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

{DD/MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

ANNEX II

OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

None

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box 1 x 1 mL and 10 x 1 mL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

NEOLEISH nasal spray, solution

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 micrograms

3. PACKAGE SIZE

1 x 1 mL
10 x 1 mL

4. TARGET SPECIES

Dogs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Nasal use

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

Thawed vial:
1 month at 2 ºC – 8 ºC within the 2 years shelf life.

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

9. SPECIAL STORAGE PRECAUTIONS

Store and transport frozen { -15 ºC to -30 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.

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

CZ Vaccines S.A.U.

14. MARKETING AUTHORISATION NUMBERS

EU/2/22/290/001 (1 x 1 ml)
EU/2/22/290/002 (10 x 1 ml)

15. 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

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each 1 mL dose contains:

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

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Thawed vial:
1 month at 2 ºC – 8 ºC within the 2 years shelf life.

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

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

NEOLEISH nasal spray, solution for dogs

2. Composition

Active substance:

Each 1 mL dose contains:

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

Colourless, transparent solution.

3. Target species

Dogs

4. Indications for use

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. Special warnings

Special warnings:
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 safe use in the target species:
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:
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.

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

7. Adverse events

Dogs
None.

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 your national reporting system: {national system details}

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

Nasal use.

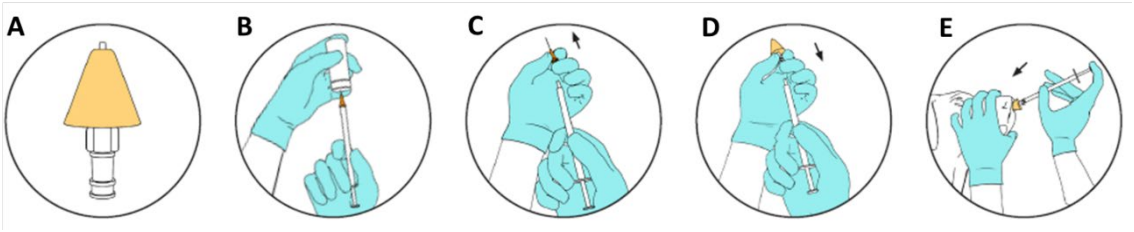
Administer one dose of 1 mL (0.5 mL/nostril) according to the following vaccination schedule:

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.

9. Advice on correct administration

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 medicine 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).

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

Frozen vial
Store and transport frozen { -15 ºC to -30 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. The expiry date refers to the last day of that month.

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

EU/2/22/290/001-002

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

Cardboard box with 10 type I glass vials containing 1 dose of 1 mL, with a butyl rubber stopper and aluminium seal.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{DD/MM/YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release:
CZ Vaccines S.A.U.
A Relva s/n – Torneiros
36410 O Porriño
Pontevedra
Spain

Local representatives and contact details to report suspected adverse reactions:
For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

España

Petia Vet Health, S.A.U.
Calle Relva s/n
36410 O Porriño
Pontevedra

España
Tel: +34 986 33 04 00

België/Belgique/Belgien, Lietuva, Република България, Luxembourg/Luxemburg, Česká republika, Magyarország, Danmark, Malta, Deutschland, Nederland, Eesti, Norge, Ελλάδα, Österreich, Polska, France, Portugal, Hrvatska, România, Ireland, Slovenija, Ísland, Slovenská republika, Italia, Suomi/Finland, Κύπρος, Sverige, Latvija, United Kingdom (Northern Ireland)

CZ Vaccines S.A.U.
A Relva s/n – Torneiros
36410 O Porriño
Pontevedra
Spain
Tel: +34 986 33 04 00

17. Other information

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.