ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Eurican L4 suspension for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One dose (1 ml) of suspension contains:

Active substances:

Inactivated *Leptospira interrogans* serogroup and serovar Canicola
strain 16070 ..... Activity acc. to Ph. Eur.447*
Inactivated *Leptospira interrogans* serogroup and serovar Icterohaemorrhagiae
strain 16069 ..... Activity acc. to Ph. Eur.447*
Inactivated *Leptospira interrogans* serogroup and serovar Grippotyphosa
strain Grippo Mal 1540.....Activity acc. to Ph. Eur.447*
Inactivated *Leptospira interrogans* serogroup Australis and serovar Bratislava
strain 16785.....Activity acc. to Ph. Eur.447*

* ≥ 80 % protection in hamsters

Excipients:

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

Opalescent and homogenous suspension.

3. CLINICAL INFORMATION

3.1 Target species

Dogs

3.2 Indications for use for each target species

Active immunisation of dogs from 7 weeks of age to prevent or reduce mortality, clinical signs, infection, bacterial excretion, renal carriage and renal lesions caused by:
- *Leptospira interrogans* serogroup Canicola serovar Canicola,
- *Leptospira interrogans* serogroup Icterohaemorrhagiae serovar Icterohaemorrhagiae,
- *Leptospira kirschneri* serogroup Grippotyphosa serovar Grippotyphosa, and
- *Leptospira interrogans* serogroup Australis serovar Bratislava.

Serogroup / Serovar	Indication					
	Mortality	**Clinical signs**	**Infection**	**Bacterial excretion**	**Renal carriage**	**Renal lesions**
Canicola / Canicola	Prevention*	Prevention*	Reduction	Reduction	Reduction	Reduction
Icterohaemorrhagiae / Icterohaemorrhagiae	Prevention*	Prevention*	Reduction	Reduction	Reduction	Reduction
Grippotyphosa / Grippotyphosa	Prevention*	Prevention*	Reduction	Reduction	Reduction	Reduction
Australis / Bratislava	Prevention	Prevention	Prevention	Prevention	Prevention	Prevention

* For *Leptospira interrogans* serovar Canicola, *Leptospira interrogans* serovar Icterohaemorrhagiae and *Leptospira kirschneri* serovar Grippotyphosa the prevention of mortality and clinical signs was not demonstrated at the duration of immunity timepoint.

Onset of immunity: 2 weeks after the second injection of the primary vaccination course for all strains.

Duration of immunity: at least one year after the second injection of the primary vaccination course for all strains.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Apply usual aseptic procedures.

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

None.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Dogs:

Very Common (>1 animal / 10 animals treated):	Injection site swelling[1], pruritus[2], injection site pain and warmth[4].
Common (1 to 10 animals / 100 animals treated):	Lethargy[3], anorexia[2] and emesis[2].
Uncommon (1 to 10 animals / 1,000 animals treated):	Diarrhoea, muscle tremor, vocalisation, hyperthermia[5], tachycardia and tachypnoea.
Rare (1 to 10 animals / 10,000 animals treated):	Hypersensitivity reactions (facial oedema, urticaria)[6].

[1] less than 6 cm, disappearing within 8 days
[2] disappearing within 2 days
[3] disappearing within 3 days
[4] disappearing within 4 days
[5] maximum 39.8 °C, disappearing within 1 day.
[6] including anaphylactic shock, which may be life threatening. If such a reaction occurs, appropriate treatment should be administered without delay.

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 section “contact details” of the package leaflet.

3.7 Use during pregnancy, lactation or lay

Safety data in pregnant bitches vaccinated with Boehringer Ingelheim’s trivalent leptospirosis vaccine containing *Leptospira Canicola, Leptospira Icterohaemorrhagiae* and *Leptospira Grippotyphosa* are available and demonstrate that it can be used during pregnancy. For Eurican L4, which contains an additional inactivated strain, *Leptospira Australis*, no safety data in pregnant bitches are available.

3.8 Interaction with other medicinal products and other forms of interaction

Safety and efficacy data are available which demonstrate that this vaccine can be mixed with Eurican DAP or Eurican DAPPi / Eurican DHPPi.
Safety and efficacy data are available which demonstrate that this vaccine can be administered on the same day as, but not mixed with Rabisin in dogs from 12 weeks of age.
No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except the products mentioned above. 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

When Eurican L4 is used alone, inject a 1 ml dose subcutaneously.
When Eurican L4 is used as a diluent of Eurican DAP or Eurican DAPPi / Eurican DHPPi, aseptically reconstitute the contents of the lyophilisate with the Eurican L4 vaccine suspension. Mix well before use. The entire contents of the reconstituted vial should be administered as a single dose.

The following schedule should be followed:

Primary vaccination: Two injections separated by an interval of 4 weeks from 7 weeks of age.

Revaccination: Administer one dose 12 months after completion of the primary vaccination course. Dogs should be revaccinated with a single booster dose on an annual basis.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

No adverse events other than those mentioned in section 3.6 were observed after administration of a 2-fold overdose. Swelling and pain at the injection site may persist longer after an overdose. These symptoms disappear within at most 22 days and 10 days respectively.

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 period(s)

Not applicable.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI07AB01

Vaccine against *Leptospira* (inactivated) in dogs.

After administration, the vaccine induces an immune response against *Leptospira interrogans* serogroup Canicola, *Leptospira interrogans* serogroup Icterohaemorrhagiae, *Leptospira kirschneri* serogroup Grippotyphosa and *Leptospira interrogans* serogroup Australis and *Leptospira interrogans* serogroup Icterohaemorrhagiae serovar Copenhageni leptospirosis in the dog, demonstrated by challenge. Prevention of mortality, clinical signs, renal infection, bacterial excretion, renal carriage and renal lesions caused by *Leptospira interrogans* serogroup Icterohaemorrhagiae serovar Copenhageni was demonstrated by challenge two weeks after vaccination. However the duration of immunity against this serovar was not established.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product except those mentioned in section 3.8 above.

5.2 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.

5.3 Special precautions for storage

Store and transport refrigerated (2 °C - 8 °C).
Do not freeze.
Protect from light.

5.4 Nature and composition of immediate packaging

Type I glass vials with chlorobutyl rubber stoppers, sealed with aluminium caps.

Plastic box of 10 vials (glass) of suspension (1 ml).
Plastic box of 50 vials (glass) of suspension (1 ml).

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal product 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

Boehringer Ingelheim Vetmedica GmbH

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/23/293/001
EU/2/23/293/002

8. DATE OF FIRST AUTHORISATION

31 March 2023

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

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 AUTORISATION

None

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Plastic box of 10 glass vials containing 1 ml of suspension
Plastic box of 50 glass vials containing 1 ml of suspension

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Eurican L4 suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Per dose (1 ml):
Inactivated *Leptospira* strains*.....activity acc. Ph.Eur.447**

**Leptospira interrogans* serogroup and serovar Canicola, Icterohaemorrhagiae, Grippotyphosa, serogroup Australis serovar Bratislava
**≥ 80 % of protection in hamsters

3. PACKAGE SIZE

10 x 1 dose: 10 x 1 ml
50 x 1 dose: 50 x 1 ml

4. TARGET SPECIES

Dogs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Subcutaneous use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {dd/mm/yyyy}
Once opened, use immediately.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
Do not freeze.
Protect from light.

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

Read 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

Boehringer Ingelheim Vetmedica GmbH

14. MARKETING AUTHORISATION NUMBER(S)

EU/2/23/293/001 10 x 1 dose
EU/2/23/293/002 50 x 1 dose

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Glass vial containing 1ml of suspension

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Eurican L4

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Leptospira interrogans
1 ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {dd/mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

1. Name of the veterinary medicinal product

Eurican L4 suspension for injection

2. Composition

One dose (1 ml) of suspension contains:

Active substances:

Inactivated *Leptospira interrogans* serogroup and serovar Canicola
strain 16070 ..... Activity acc. to Ph. Eur.447*
Inactivated *Leptospira interrogans* serogroup and serovar Icterohaemorrhagiae
strain 16069 ..... Activity acc. to Ph. Eur.447*
Inactivated *Leptospira interrogans* serogroup and serovar Grippotyphosa
strain Grippo Mal 1540 ..... Activity acc. to Ph. Eur.447*
Inactivated *Leptospira interrogans* serogroup Australis and serovar Bratislava
strain 16785 ..... Activity acc. to Ph. Eur.447*

* ≥ 80 % protection in hamsters

Opalescent and homogenous suspension.

3. Target species

Dogs

4. Indications for use

Active immunisation of dogs from 7 weeks of age to prevent or reduce mortality, clinical signs, infection, bacterial excretion, renal carriage and renal lesions caused by:
- *Leptospira interrogans* serogroup Canicola serovar Canicola,
- *Leptospira interrogans* serogroup Icterohaemorrhagiae serovar Icterohaemorrhagiae,
- *Leptospira kirschneri* serogroup Grippotyphosa serovar Grippotyphosa, and
- *Leptospira interrogans* serogroup Australis serovar Bratislava.

Serogroup / Serovar	**Indication**					
	Mortality	**Clinical signs**	**Infection**	**Bacterial excretion**	**Renal carriage**	**Renal lesions**
Canicola / Canicola	Prevention*	Prevention*	Reduction	Reduction	Reduction	Reduction
Icterohaemorrhagiae / Icterohaemorrhagiae	Prevention*	Prevention*	Reduction	Reduction	Reduction	Reduction
Grippotyphosa / Grippotyphosa	Prevention*	Prevention*	Reduction	Reduction	Reduction	Reduction
Australis / Bratislava	Prevention	Prevention	Prevention	Prevention	Prevention	Prevention

* For *Leptospira interrogans* serovar Canicola, *Leptospira interrogans* serovar Icterohaemorrhagiae, and *Leptospira kirschneri serovar* Grippotyphosa, the prevention of mortality and clinical signs was not demonstrated at the duration of immunity timepoint.

Onset of immunity: 2 weeks after the second injection of the primary vaccination course for all strains.

Duration of immunity: at least one year after the second injection of the primary vaccination course for all strains.

5. Contraindications

None.

6. Special warnings

Vaccinate healthy animals only.

Special precautions for safe use in the target species:
Apply usual aseptic procedures.

Pregnancy:
Safety data in pregnant bitches vaccinated with Boehringer Ingelheim's trivalent leptospirosis vaccine containing *Leptospira* Canicola, *Leptospira* Icterohaemorrhagiae and *Leptospira* Grippotyphosa are available and demonstrate that it can be used during pregnancy. For Eurican L4, which contains an additional inactivated strain, *Leptospira* Australis, no safety data in pregnant bitches are available.

Interaction with other medicinal products and other forms of interaction:
Safety and efficacy data are available which demonstrate that this vaccine can be mixed with Eurican DAP or Eurican DAPPi / Eurican DHPPi.
Safety and efficacy data are available which demonstrate that this vaccine can be administered on the same day as, but not mixed with, Rabisin in dogs from 12 weeks of age.
No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except the products mentioned above. 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:
No adverse events other than those mentioned in section "adverse events" were observed after administration of a 2-fold overdose. Swelling and pain at the injection site may persist longer after an overdose. These symptoms disappear within at most 22 days and 10 days respectively.

Major incompatibilities:
Do not mix with any other veterinary medicinal product except Eurican DAP or Eurican DAPPi / Eurican DHPPi.

7. Adverse events

Dogs:

- Very Common (>1 animal / 10 animals treated): Injection site swelling (less than 6 cm) disappearing within 8 days, pruritus disappearing within 2 days, injection site pain and warmth, disappearing within 4 days.

- Common (1 to 10 animals / 100 animals treated): lethargy disappearing within 3 days, anorexia and emesis disappearing within 2 days.

- Uncommon (1 to 10 animals / 1,000 animals treated): Diarrhoea, muscle tremor, vocalisation, hyperthermia (maximum 39.8°C lasting at most 1 day), tachycardia and tachypnoea.

- Rare (1 to 10 animals / 10,000 animals treated): Hypersensitivity reactions (facial oedema, urticaria) including anaphylactic shock, which may be life-threatening. If such a reaction occurs, appropriate treatment should be administered without delay.

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 representatives 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

When Eurican L4 is used alone, inject a 1 ml dose subcutaneously according to the following schedule:

Primary vaccination: Two injections separated by an interval of 4 weeks from 7 weeks of age.

Revaccination: Administer one dose 12 months after completion of the primary vaccination course. Dogs should be revaccinated with a single booster dose on an annual basis.

9. Advice on correct administration

When Eurican L4 is used as a diluent of Eurican DAP or Eurican DAPPi / Eurican DHPPi, aseptically reconstitute the contents of the lyophilisate with the Eurican L4 vaccine suspension. Mix well before use. The entire contents of the reconstituted vial should be administered as a single dose.

10. Withdrawal periods

Not applicable

11. Special storage precautions

Keep out of the sight and reach of children.
Store and transport refrigerated (2 °C - 8 °C).
Do not freeze.
Protect from light.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp.
Shelf-life after first opening the immediate packaging: 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.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. 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).

14. Marketing authorisation numbers and pack sizes

EU/2/23/293/001
EU/2/23/293/002

Plastic box of 10 vials (glass) of suspension (1 ml).
Plastic box of 50 vials (glass) of suspension (1 ml).

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

16. Contact details

Marketing authorisation holder:
Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
Germany

Manufacturer responsible for batch release:
Boehringer Ingelheim Animal Health France SCS
Laboratoire Porte des Alpes
Rue de l'Aviation
69800 Saint-Priest
France

Local representatives and contact details to report suspected adverse events:

België/Belgique/Belgien
Boehringer Ingelheim Animal Health Belgium SA
Avenue Arnaud Fraiteurlaan 15-23,
1050 Bruxelles/Brussel/Brüssel
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Tel: +353 1 291 3985

17. Other information

ATCvet code: QI07AB01.
Vaccine against *Leptospira* (inactivated) in dogs.
After administration, the vaccine induces an immune response against *Leptospira interrogans* serogroup Canicola, *Leptospira interrogans* serogroup Icterohaemorrhagiae, *Leptospira kirschneri* serogroup Grippotyphosa, *Leptospira interrogans* serogroup Australis and *Leptospira interrogans* serogroup Icterohaemorrhagiae serovar Copenhageni leptospirosis in the dog, demonstrated by challenge.
Prevention of mortality, clinical signs, renal infection, bacterial excretion, renal carriage and renal lesions caused by *Leptospira interrogans* serogroup Icterohaemorrhagiae serovar Copenhageni was demonstrated by challenge two weeks after vaccination. However the duration of immunity against this serovar was not established.