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 AND OTHER SUBSTANCES

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

**Leptospira* 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. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Subcutaneous use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {dd/mm/yyy}
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 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 AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH

14. MARKETING AUTHORISATION NUMBERS

Vm 04491/5063

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS (Glass vial containing 1 ml of suspension)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Eurican L4 

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)

1 ml

3. BATCH NUMBER

Lot

4. EXPIRY DATE

Exp.

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

6. ROUTE(S) OF ADMINISTRATION

7. WITHDRAWAL PERIOD

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only

PARTICULARS TO APPEAR ON THE 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, no mortality and clinical signs occurred in the vaccinated and control groups during challenge experiment for duration of immunity.
** For *Leptospira interrogans* serovar Icterohaemorrhagiae and *Leptospira kirschneri* serovar Grippotyphosa, no mortality occurred in the vaccinated and control groups during challenge experiments for duration of immunity and the prevention of clinical signs was not statistically significant.

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 WARNING(S)

Vaccinate healthy animals only.

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

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

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 Boehringer Ingelheim live attenuated vaccines against distemper, adenovirosis, parvovirosis and parainfluenza type 2 respiratory infections.
Safety and efficacy data are available which demonstrate that this vaccine can be administered on the same day as, but not mixed with, Boehringer Ingelheim's rabies vaccine 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.

Major incompatibilities:
Do not mix with any other veterinary medicinal product except Boehringer Ingelheim live attenuated vaccines against distemper, adenovirosis, parvovirosis and parainfluenza type 2 respiratory infections.

7. ADVERSE EVENTS

Very common (>1 animal / 10 animals treated):
Swelling at the injection site disappearing within 22 days, transient pruritus, heat and pain at the injection site disappearing within 10 days,

Common (1 to 10 animals / 100 animals treated):
transient lethargy, anorexia and emesis.

Uncommon (1 to 10 animals / 1,000 animals treated):
Diarrhoea, muscle tremor, vocalisation, hyperthermia tachycardia and tachypnoea

Rare (1 to 10 animals / 10,000 animals treated):
Hypersensitivity reactions (facial oedema, anaphylactic shock, urticaria), some of which are life-threatening. Appropriate symptomatic treatment should promptly be provided.

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 using the contact details at the end of this leaflet, or via your national reporting system.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) 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 a Boehringer Ingelheim freeze-dried vaccine against distemper, adenovirosis, parvovirosis and parainfluenza type 2, 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 PERIOD(S)

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements. Medicines should not be disposed of via wastewater or household waste.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

POM-V

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 04491/5063

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

MM/YYYY

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 reactions:
United Kingdom (Great Britain)
Boehringer Ingelheim Animal Health UK Ltd
Bracknell, RG12 8YS
+44 1344 746957

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 leptospirosis in the dog demonstrated by challenge.

Approved 21 June 2023