PARTICULARS TO APPEAR ON THE OUTER PACKAGE (10x CARTON)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Eurican L

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Inactivated *Leptospira canicola* and inactivated *Leptospira icterohaemorrhagiae* ≥ 80% protection, Excipient q.s. 1 dose of 1 ml.

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

10 x 1 dose

5. TARGET SPECIES

Dogs from 8 weeks of age

6. INDICATION(S)

Inactivated canine leptospirosis vaccine

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Suspension for injection. 1 ml SC.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

11. SPECIAL STORAGE CONDITIONS

Store at 2°C - 8°C (in a refrigerator), protected from light.

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

Dispose of waste material in accordance with national requirements.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

[Distribution category]

For animal treatment only – to be supplied only on veterinary prescription.

UK: POM-V

IE: POM

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

Boehringer Ingelheim Vetmedica GmbH, 55216 Ingelheim/Rhein, Germany

16. MARKETING AUTHORISATION NUMBER(S)

Vm 08327/4148

VPA 10454/041/001

17. MANUFACTURER'S BATCH NUMBER

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS (VIAL LABEL)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Eurican L

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Inactivated canine leptospirosis vaccine (*L. icterohaemorrhagiae* and *L. canicola*)

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

One dose

4. ROUTE(S) OF ADMINISTRATION

S.C. injection

5. WITHDRAWAL PERIOD

6. BATCH NUMBER

Batch

7. EXPIRY DATE

Exp.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only

9. FURTHER INFORMATION

POM-V

Boehringer Ingelheim

PACKAGE LEAFLET FOR:
Eurican L Suspension for Injection

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing Authorisation holder
Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

Boehringer Ingelheim Vetmedica GmbH, 55216 Ingelheim/Rhein, Germany

Manufacturer for the batch release
Boehringer Ingelheim Animal Health France SCS
Laboratoire Portes des Alpes
Rue de l'Aviation
69800 Saint Priest
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Eurican L
Suspension for injection

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

Each 1 ml of vaccine contains:
- Inactivated *Leptospira canicola* ....
- Inactivated *Leptospira icterohaemorrhagiae*…

*≥80% protection**

- Excipient ..... qs 1 dose of 1 ml

* According to Ph. Eur. hamster potency test

4. INDICATION(S)

In dogs: active immunisation against *Leptospira canicola* and *Leptospira icterohaemorrhagiae* to prevent mortality and to reduce clinical symptoms of Leptospira infections caused by these agents.
Onset of immunity: 14 days after primary vaccination.
The duration of immunity is one year.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

In rare cases, immediately after injection, transient pain may occur at the injection site. A temperature increase of approximately 1°C lasting no more than a day may occur in rare cases. In rare circumstances a hypersensitivity reaction may occur, which may require appropriate symptomatic treatment. No other adverse events were reported following administration of an overdose of the vaccine, except transitory and slight swelling at the injection site. If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs from 8 weeks of age.

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

Inject by subcutaneous route a 1-ml dose according to the following schedule:
Basic vaccination
1st injection: from 8 weeks of age.
2nd injection: 3 to 5 weeks later, from 12 weeks of age.
Revaccination
Annual boosters by administration of a single 1 ml dose.

9. ADVICE ON CORRECT ADMINISTRATION

Eurican L may be used as a diluent for Eurican P or Eurican DHPPi vaccines as part of a full vaccination programme.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Store and transport at 2°C – 8°C (in a refrigerator), protected from light. Do not use after the expiry date stated on the label.
Keep out of the reach and sight of children.

12. SPECIAL WARNING(S)

Vaccinate only healthy animals.
In the absence of data from studies in seronegative bitches, the vaccine should only be used in pregnant bitches which have been vaccinated before pregnancy.
Safety and efficacy data are available which demonstrate that this vaccine can be used as a diluent for Eurican P or Eurican DHPPi. 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.
Do not mix with any other medicinal product except Eurican DHPPi and Eurican P.
In the case of accidental self-injection, wash the area immediately with water.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste material derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

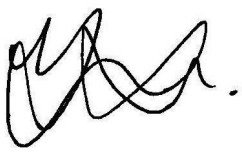
April 2020

15. OTHER INFORMATION

Pack sizes:
1 dose glass bottle, box of 10 bottles
1 dose glass bottle, box of 50 bottles
Not all pack sizes may be marketed.

UK: POM-V Vm 08327/4148

IE POM VPA10454/041/001



Approved: 27 May 2020