ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Plastic box of 10 vials (glass) of 1 ml of suspension.
Plastic box of 25 vials (glass) of 1 ml of suspension.
Plastic box of 50 vials (glass) of 1 ml of suspension.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Eurican Lmulti Suspension for Injection

2. STATEMENT OF ACTIVE SUBSTANCES

Per dose:
Inactivated *Leptospira* strains* ..... activity acc. Ph.Eur.447**

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

3. PHARMACEUTICAL FORM

Suspension for injection.

4. PACKAGE SIZE

10 doses : 10x1ml suspension.
25 doses : 25x1ml suspension.
50 doses : 50x1ml suspension.

5. TARGET SPECIES

Dogs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Not applicable

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once opened, use immediately.

11. SPECIAL STORAGE CONDITIONS

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

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

Disposal : Read package leaflet.

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

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

16. MARKETING AUTHORISATION NUMBER(S)

08327/4264

17. MANUFACTURER'S BATCH NUMBER

Lot

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Suspension:1 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Eurican Lmulti

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Lmulti
Read package leaflet before use.

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

1 ml

4. ROUTE(S) OF ADMINISTRATION

SC

5. WITHDRAWAL PERIOD(S)

Not applicable

6. BATCH NUMBER

Lot:

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
EURICAN Lmulti
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

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Eurican L_{multi}
Suspension for injection.

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

One dose (1ml) of suspension contains:

Inactivated *Leptospira interrogans* serogroup and serovar Canicola
strain 16070 .....Activity acc. to Ph. Eur.447*
Inactivated *Leptospira interrogans* serogroup and serovar Icterohaemorrhagiae
strain16069 .....Activity acc. to Ph. Eur.447*
Inactivated *Leptospira interrogans* serogroup and serovar Grippotyphosa
strain Grippo Mal 1540 .....Activity acc. to Ph. Eur.447*
*≥80% protection in hamsters

Opalescent, homogenous suspension.

4. INDICATION(S)

Active immunisation of dogs to:

- prevent mortality, clinical signs, infection, bacterial excretion, renal carriage and renal lesions caused by *Leptospira interrogans* serogroup Icterohaemorrhagiae serovar Icterohaemorrhagiae
- prevent mortality* and clinical signs, reduce infection, bacterial excretion, renal carriage and renal lesions caused by *Leptospira interrogans* serogroup Canicola serovar Canicola.
- prevent mortality*, and reduce clinical signs, infection, bacterial excretion renal carriage and renal lesions caused by *Leptospira kirschneri* serogroup Grippotyphosa serovar Grippotyphosa.

- prevent mortality, clinical signs, renal infection, bacterial excretion, renal carriage and renal lesions caused by *Leptospira interrogans* serogroup Icterohaemorrhagiae serovar Copenhageni.**

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.
* For *Leptospira* Canicola and Grippotyphosa, no mortality occurred during challenge experiment for duration of immunity.
** For *Leptospira* Copenhageni the duration of immunity was not established.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

A slight swelling (≤ 2 cm) at the injection site may commonly be observed immediately after injection.It usually regresses within 1-6 days. This can, on some occasions, be accompanied by slight pruritus, heat and pain at the injection site. Transient lethargy and emesis may also commonly be observed.

Anorexia, polydipsia, hyperthermia, diarrhoea, muscle tremor, muscle weakness and injection site cutaneous lesions may uncommonly be observed.

Hypersensitivity reactions (facial oedema, anaphylactic shock, urticaria) may rarely occur, some of which are life-threatening. Appropriate symptomatic treatment should promptly be provided.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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 inform your veterinary surgeon. Alternatively you can report via your national reporting system.

7. TARGET SPECIES

Dogs

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

When Eurican L_{multi} 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 L_{multi} 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 suspension for injection. Shake 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 WARNING(S)

Special warnings for each target species:
Vaccinate healthy animals only.

Special precautions for use in animals:
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: Can be used during pregnancy

Interaction with other medicinal products and other forms of interaction:
The product 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 but not mixed with Boehringer Ingelheim's rabies vaccine in dogs from 12 weeks of age. In that case, the efficacy against *Leptospira* Icterohaemorrhagiae was demonstrated only for the reduction of renal lesions and bacterial excretion, and the efficacy against *Leptospira* Grippotyphosa was demonstrated only for the reduction of renal carriage, renal lesions and bacterial excretion. Efficacy of the vaccine for protection against the Copenhageni serovar has not been investigated after use with Boehringer Ingelheim's rabies vaccine on the same day.
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 reactions other than those mentioned in section 'adverse reactions" were observed after administration of a 2-fold overdose.

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.

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

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.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

June 2020

15. OTHER INFORMATION

Plastic box of 10 vials (glass) of suspension(1 ml).
Plastic box of 25 vials (glass) of suspension (1 ml).
Plastic box of 50 vials (glass) of suspension (1 ml).

Not all pack sizes may be marketed.

Approved 09 September 2020