SUMMARY OF PRODUCT CHARACTISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

EURICAN L

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Inactivated *Leptospira canicola*.....} ≥ 80% protection*
Inactivated *Leptospira icterohaemorrhagiae*.....}
Excipient……q.s. 1 dose of 1ml

*According to Ph. Eur. hamster potency test

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Suspension for injection.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs from 8 weeks of age.

4.2 Indications for use specifying the target species

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.

4.3 Contra-indications

None

4.4 Special warnings for each target species

None.

4.5 Special precautions for use, including special precautions to be taken by the person administering the medicinal product to animals

i. Special precautions for use in animals

Vaccinate only healthy animals.

ii. Special precautions to be taken by the person administering the medicinal product to the animals

In the case of accidental self-injection, wash the area immediately with water.

4.6 Adverse reactions (frequency and seriousness)

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.

4.7 Use during pregnancy, lactation or lay

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.

4.8 Interaction with other medicinal products and other forms of interaction

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.

4.9 Amounts to be administered and administration route

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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

No adverse events, other than those reported in Section 4.6 for a single dose, were reported following administration of an overdose of the vaccine, except transitory and slight swelling at the injection site.

4.11 Withdrawal periods

Not applicable

5. IMMUNOLOGICAL PROPERTIES

The vaccine stimulates active immunity against *Leptospira canicola* and *Leptospira icterohaemorrhagiae* leptospiroses.

ATC Vet Code: QI07AB01

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Phosphate buffered saline.

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal product except Eurican DHPPi and Eurican P.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.

6.4 Special precautions for storage

Store and transport at 2ºC – 8ºC (in a refrigerator), protected from light.

6.5 Nature and composition of immediate packaging

Type 1 glass bottle
Butyl elastomer closure

Bottle (glass) of 1 dose of suspension, box of 10 bottles
Bottle (glass) of 1 dose of suspension, box of 50 bottles

Not all pack sizes may be marketed.

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

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

7. MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Ltd
Ellesfield Avenue
Bracknell
Berkshire
RG12 8YS

8. MARKETING AUTHORISATION NUMBER

Vm 08327/4148

9. DATE OF FIRST AUTHORISATION

28 October 2005

10. DATE OF REVISION OF THE TEXT

November 2018

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable

Approved 01 November 2018