Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Eurican L

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Inactivated *Leptospira canicola*..... } ≥ 80% protection*
Inactivated *Leptospira icterohaemorrhagiae*..... }
Excipient..... qs 1 dose of 1 ml
*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 Contraindications

None.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

(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 interactions

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. 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 period(s)

Not applicable.

5 PHARMACOLOGICAL or 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 2°C – 8°C (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 products 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 Vetmedica GmbH
Binger Strasse 173
55216 Ingelheim am Rhein
Germany

8 MARKETING AUTHORISATION NUMBER(S)

VPA10454/041/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 5 November 2004
Date of last renewal: 2 October 2009

10 DATE OF REVISION OF THE TEXT

December 2018