SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Eurican L4 suspension for injection

2. QUALITATIVE AND QUANTITATIVE 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

Excipients:

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Suspension for injection.
Opalescent and homogenous suspension.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs

4.2 Indications for use, specifying the target species

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.

4.3 Contraindications

None

4.4 Special warnings for each target species

Vaccinate healthy animals only

4.5 Special precautions for use

i). Special precautions for safe use in the target species

Apply usual aseptic procedures

ii). 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 label to the physician.

iii). Other precautions

4.6 Adverse reactions (frequency and seriousness)

Very common (>1 animal / 10 animals treated):	Swelling at the injection site[1], transient pruritus, heat and pain at the injection site[2]
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[3].

[1] disappearing within 22 days
[2] disappearing within 10 days
[3] appropriate symptomatic treatment should promptly be provided.

4.7 Use during pregnancy, lactation or lay

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

4.9 Amount(s) to be administered and administration route

When Eurican L4 is used alone, inject a 1 ml dose subcutaneously.
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.

The following schedule should be followed:

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.

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

No adverse events other than those mentioned in section 4.6 were observed after administration of a 2-fold overdose.

4.11 Withdrawal period(s)

Not applicable.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for Canidae, Inactivated bacterial vaccines for dogs.

ATC vet vode: 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 and Leptospira interrogans serogroup Australis leptospirosis in the dog demonstrated by challenge.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Potassium chloride
Sodium chloride
Potassium dihydrogen phosphate
Disodium phosphate dihydrate
Water for injections

6.2 Major Incompatibilities

Do not mix with any other veterinary medicinal product except those listed in section 4.8.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale:2 years.
Shelf life after first opening the immediate packaging: use immediately.

6.4 Special precautions for storage

Store and transport refrigerated (2 ^{o}C – 8 ^{o}C).
Do not freeze.
Protect from light.

6.5 Nature and composition of immediate packaging

Type I glass vials with chlorobutyl rubber stoppers, sealed with aluminium caps.

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.

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 materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH
Binger Strasse 173
55216 Ingelheim Rhein
Germany

8. MARKETING AUTHORISATION NUMBER

Vm 04491/5063

9. DATE OF FIRST AUTHORISATION

02 June 2023

10. DATE OF REVISION OF THE TEXT

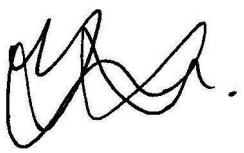
August 2023

PROHIBITION OF SALE, SUPPLY AND/OR USE

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

POM-V

Veterinary medicinal product subject to prescription.



Approved: 10 August 2023