

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Eurican Lmulti Suspension for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One dose (1ml) of suspension contains:

Active substances:

Inactivated *Leptospira interrogans* serogroup and serovar Canicola strain 16070Activity acc. to Ph. Eur.447*
Inactivated *Leptospira interrogans* serogroup and serovar Icterohaemorrhagiae strain16069Activity acc. to Ph. Eur.447*
Inactivated *Leptospira interrogans* serogroup and serovar Grippotyphosa strain Grippo Mal 1540Activity 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 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.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Vaccinate healthy animals only.

4.5 Special precautions for use

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.

4.6 Adverse reactions (frequency and seriousness)

A slight swelling (≤ 2 cm) at the injection site may commonly be observed 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).

4.7 Use during pregnancy, lactation or lay

Can be used during pregnancy

4.8 Interaction with other medicinal products and other forms of interaction

The product can be mixed with Boehringer Ingelheim live attenuated vaccines against distemper, adenovirus, parvovirus 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

4.9 Amounts to be administered and administration route

When Eurican Lmulti is used alone, inject a 1-ml dose subcutaneously

When Eurican Lmulti is used as a diluent of a Boehringer Ingelheim freeze-dried vaccine against distemper, adenovirus, parvovirus 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.

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 other adverse reactions 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.

ATCvet code: 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 interrogans* serogroup Copenhageni and *Leptospira kirschneri* serogroup Grippotyphosa 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 °C- 8 °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 25 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 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 08327/4264

9. DATE OF FIRST AUTHORISATION

10 December 2015

10. DATE OF REVISION OF THE TEXT

September 2020

A handwritten signature in black ink, consisting of several loops and a long horizontal stroke extending to the right.

Approved 09 September 2020