17 February 2023
EMA/CVMP/54218/2023
Committee for Veterinary Medicinal Products

Summary of opinion[1] (initial authorisation)

Eurican L4

Common name: Canine leptospirosis vaccine (inactivated)

On 15 February 2023, the Committee for Veterinary Medicinal Products (CVMP) adopted a positive opinion[2], recommending the granting of a marketing authorisation for the veterinary medicinal product Eurican L4, suspension for injection, intended for dogs. The applicant for this veterinary medicinal product is Boehringer Ingelheim Vetmedica GmbH.

Eurican L4 is an inactivated immunological veterinary medicinal product containing *Leptospira interrogans*, serogroup Canicola, serovar Canicola, strain 16070, *L. interrogans*, serogroup icterohaemorrhagiae, serovar icterohaemorrhagiae, strain 16069, *L. interrogans*, serogroup Grippotyphosa, serovar Grippotyphosa, strain Grippo Mal 1540, *L. interrogans*, serogroup Australis, serovar Bratislava, strain 16785 (ATCvet code QI07AB01) as active substances. After administration, the vaccine induces an immune response against *Leptospira interrogans* serogroup Canicola, *L. interrogans* serogroup Icterohaemorrhagiae, *L. kirschneri* serogroup Grippotyphosa and *L. interrogans* serogroup Australis and *L. interrogans* serogroup Icterohaemorrhagiae serovar Copenhageni leptospirosis in the dog, demonstrated by challenge.

The benefit of Eurican L4 is the prevention or reduction of mortality, clinical signs, infection, bacterial excretion, renal carriage and renal lesions caused by three different serovars of *Leptospira interrogans* and one serovar of *Leptospira kirschneri* in dogs from 7 weeks of age. The most common side effects are injection site swelling, pruritus, injection site pain and warmth.

The full indication is: 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.

[1] Summaries of opinion are published without prejudice to the Commission Decision, which will normally be issued 67 days from adoption of the opinion.
[2] Applicants may appeal any CVMP opinion, provided they notify the European Medicines Agency in writing of their intention to appeal within 15 days of receipt of the opinion.

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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, *Leptospira interrogans* serovar Icterohaemorrhagiae and *Leptospira kirschneri* serovar Grippotyphosa the prevention of mortality and clinical signs was not demonstrated at the duration of immunity timepoint.

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.

Detailed conditions for the use of this product are described in the summary of product characteristics (SPC) which will be published in the Union Product Database (UPD) and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CVMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit-risk balance for Eurican L4 and therefore recommends the granting of the marketing authorisation.