6 October 2023
EMA/CVMP/424834/2023
Committee for Veterinary Medicinal Products

Summary of opinion[1] (initial authorisation)

Nobivac LoVo L4

Common name: Canine leptospira vaccine

On 5 October 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 Nobivac LoVo L4, suspension for injection, intended for dogs. The applicant for this veterinary medicinal product is Intervet International B.V.

Nobivac LoVo L4 is an immunological veterinary medicinal product containing *Leptospira interrogans*, serogroup Canicola, serovar Portland-vere, strain Ca-12-000, inactivated, *L. interrogans*, serogroup Icterohaemorrhagiae, serovar Copenhageni, strain Ic-02-001, inactivated, *L. interrogans*, serogroup Australis, serovar Bratislava, strain As-05-073, inactivated and *Leptospira kirschneri*, serogroup Grippotyphosa, serovar Dadas, strain GR-01-005, inactivated (ATCvet code QI07AB01) as active substances.

The benefit of Nobivac LoVo L4 is the stimulation of the active immunisation of dogs against *L. interrogans* serogroup Canicola serovar Canicola, *L. interrogans* serogroup Icterohaemorrhagiae serovar Copenhageni, *L. interrogans* serogroup Australis serovar Bratislava, and *L. kirschneri* serogroup Grippotyphosa serovar Bananal/Liangguang. In vitro and in vivo data in non-target species suggest that the vaccine may provide a degree of cross-protection against *L. interrogans* serogroup Icterohaemorrhagiae serovar Icterohaemorrhagiae and *L. kirschneri* serogroup Grippotyphosa serovar Grippotyphosa. The most common side effects are injection site swelling, injection site nodule, injection site pain, elevated temperature, decreased activity and decreased appetite. In very rare cases, hypersensitivity reaction, immune mediated haemolytic anaemia, immune mediated thrombocytopenia or immune mediated polyarthritis may occur.

Nobivac LoVo L4 is a duplicate of Nobivac L4, which has been authorised in the EU since 16 July 2012.

The full indication is: For active immunisation of dogs against:

[1] Summaries of opinion are published without prejudice to the Commission Decision.
[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.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

- *L. interrogans* serogroup Canicola serovar Canicola to reduce infection and urinary excretion
- *L. interrogans* serogroup Icterohaemorrhagiae serovar Copenhageni to reduce infection and urinary excretion
- *L. interrogans* serogroup Australis serovar Bratislava to reduce infection
- *L. kirschneri* serogroup Grippotyphosa serovar Bananal/Lianguang to reduce infection and urinary excretion.

Onset of immunity: 3 weeks.
Duration of immunity: 1 year.

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 Nobivac LoVo L4 and therefore recommends the granting of the marketing authorisation.