13 June 2025
EMADOC-1700519818-2188844
Committee for Veterinary Medicinal Products (CVMP)

Summary of opinion[1] (post-authorisation)

Nobivac L4

Vaccine common name: Canine leptospirosis vaccine (inactivated)

On 12 June 2025, the Committee for Veterinary Medicinal Products (CVMP) adopted an opinion[2], recommending the change to the terms of the marketing authorisations for the veterinary medicinal products Nobivac L4 and Nobivac LoVo L4, following worksharing procedure for a group of variations. The marketing authorisation holder for this veterinary medicinal product is Intervet International B.V..

Nobivac L4 and Nobivac LoVo L4 are currently authorised for the active immunisation of dogs against:

- *Leptospira 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/Liangguang to reduce infection and urinary excretion.

The proposed variation is to add a new therapeutic indication or modification of an approved one for 2 new Leptospira serovars, existing Leptospira serovars, addition of efficacy against serovar Australis and associated non-mixed use with Nobivac Rabies (Nationally registered). A consequential name update from L4 to L6 is also proposed.

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

[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.

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