21 May 2012
EMA/CVMP/282463/2012
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1]

Nobivac L4

Vaccine to prevent Leptospira infections in dogs

On 16 May 2012, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion,[2] recommending the granting of a marketing authorisation for the veterinary medicinal product Nobivac L4, suspension for injection, intended for active immunisation of dogs to prevent infection and urinary excretion caused by 4 different Leptospira strains. The applicant for this veterinary medicinal product is Intervet International BV.

The active substances of Nobivac L4 are the following 4 inactivated *Leptospira* strains

- *L. interrogans* serogroup Canicola serovar Portland-vere (strain Ca-12-000) 3550-7100 U[1]
- *L. interrogans* serogroup Icterohaemorrhagiae serovar Copenhageni (strain Ic-02-001) 290-1000 U[1]
- *L. interrogans* serogroup Australis serovar Bratislava (strain As-05-073) 500-1700 U[1]
- *L. kirschneri* serogroup Grippotyphosa serovar Dadas (strain Gr-01-005) 650-1300 U[1]

[1] Antigenic mass ELISA units.

The ATCvet code for this immunological medicinal product is QI07AB01 and benefits of the vaccine are the active immunisation of dogs against:

- *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

[1] Summaries of opinion are published without prejudice to the Commission Decision, which will normally be issued within 90 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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The most common side effects are a mild and transient increase in body temperature (≤ 1°C) for a few days after vaccination, with some pups showing less activity and/or a reduced appetite. A small transient swelling (≤ 4 cm), which can occasionally be firm and painful on palpation, may be observed at the site of injection. Any such swelling will either have disappeared or be clearly diminished by 14 days post-vaccination. An occasional transient acute hypersensitivity (anaphylaxis) reaction may occur.

Detailed conditions for the use of this product will be described in the summary of product characteristics (SPC) which will be published in the European public assessment report (EPAR) 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 to risk balance for Nobivac L4 and therefore recommends the granting of the marketing authorisation.