8 May 2015
EMA/CVMP/259133/2015
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

Canigen L4

Common name: Canine leptospirosis vaccine (inactivated)

On 7 May 2015, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the veterinary medicinal product Canigen L4, suspension for injection, intended for active immunisation of dogs to reduce infection and urinary excretion caused by 4 different *Leptospira* strains. The applicant for this veterinary medicinal product is Intervet International B.V. They may request a re-examination of the CVMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

Canigen L4 is a bacterial vaccine containing inactivated *L. interrogans* serogroup Canicola serovar Portland-vere (strain Ca-12-000), inactivated *L. interrogans* serogroup Icterohaemorragiae serovar Copenhageni (strain Ic-02-001), inactivated *L. interrogans* serogroup Australis serovar Bratislava (strain As-05-073) and inactivated *L. kirschneri* serogroup Grippotyphosa serovar Dadas (strain Gr-01-005) (ATCvet code QI07AB01) as active substance.

The benefit of Canigen L4 is its efficacy in the active immunisation of dogs against *L. interrogans* serogroup Canicola serovar Canicola, *L. interrogans* serogroup Icterohaemorrhagiae serovar Copenhageni and *L. kirschneri* serogroup Grippotyphosa serovar Bananal/Lianguang to reduce infection and urinary excretion and against *L. interrogans* serogroup Australis serovar Bratislava to reduce infection. The most common side effects are a mild and transient increase in body temperature (≤ 1°C) that may occur 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), 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

[1] Summaries of opinion are published without prejudice to the Commission Decision, which will normally be issued 67 days from adoption of the opinion.

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by the European Commission.

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