14 January 2011
EMA/CVMP/296014/2010
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1]

CaniLeish

Leishmania infantum excreted secreted proteins (ESP)

On 12 January 2011, 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 CaniLeish, a lyophilisate and solvent for suspension for injection, intended for the active immunisation of Leishmania negative dogs from 6 months of age to reduce the risk to develop an active infection and clinical disease after contact with *Leishmania infantum*. The applicant for this veterinary medicinal product is Virbac S.A.

The active substance of CaniLeish is *Leishmania infantum* excreted secreted proteins (ESP).

The benefits of CaniLeish are the stimulation of active immunity in Leishmania negative dogs from 6 months of age to reduce the risk to develop an active infection and clinical disease after contact with *Leishmania infantum*. The most common side effects are, moderate and transient local reactions that may occur after injection such as swelling, nodule, pain on palpation or erythema. These reactions resolve spontaneously within 2 to 15 days. Other transient signs commonly seen following vaccination may be observed such as hyperthermia, apathy and digestive disorders lasting 1 to 6 days. Allergic-type reactions are uncommon and appropriate symptomatic treatment should then be administered.

The approved indication is:

“For the active immunisation of Leishmania negative dogs from 6 months of age to reduce the risk to develop an active infection and clinical disease after contact with *Leishmania infantum*.

The efficacy of the vaccine has been demonstrated in dogs submitted to multiple natural parasite exposure in zones with high infection pressure.

Onset of immunity: 4 weeks after the primary vaccination course

Duration of immunity: 1 year after the last (re-)vaccination”.

[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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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 CaniLeish and therefore recommends the granting of the marketing authorisation.