EMA/296055/2010
EMEA/V/C/002232

EPAR summary for the public

CaniLeish

Canine vaccine against *Leishmania infantum* adjuvanted

This document is a summary of the European Public Assessment Report. Its purpose is to explain how the assessment done by the Committee for Medicinal Products for Veterinary Use (CVMP) on the basis of the documentation provided, led to the recommendations on the conditions of use.

This document cannot replace a face-to-face discussion with your veterinarian. If you need more information about your animal's medical condition or treatment, contact your veterinarian. If you want more information on the basis of the CVMP recommendations, read the Scientific Discussion (also part of the EPAR).

What is CaniLeish?

CaniLeish is a vaccine. It is available as a powder and solvent that is made up into suspension for injection. It contains *Leishmania infantum* excreted secreted proteins (ESP).

What is CaniLeish used for?

CaniLeish is used to vaccinate dogs from six months of age to reduce the risk of developing an active infection and clinical disease after contact with *Leishmania infantum*.

Leishmania infantum is a parasite that causes leishmaniosis. It is widespread in countries bordering the Mediterranean Sea. The parasite is transmitted from an infected dog to a non-infected dog by the bites of sand flies. Dogs that have been infected may show no signs of infection, but some do (fever, hair and weight loss, skin sores) and in the latter case the outcome of active infection can be fatal. Infected dogs play a central role in the accidental transmission of parasites to humans.

CaniLeish is to be used only in 'leishmania-negative' dogs. The detection of Leishmania infection using a rapid diagnostic test is recommended before vaccination.

The vaccine is given to dogs as three injections, three weeks apart, under the skin. The first injection can be given from six months of age, the second injection is given three weeks later and the third three weeks from the second one. Afterward a single 'booster' should be given every year to maintain

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

the vaccine's effect. Veterinarians should assess the benefit-risk balance before vaccinating dogs in areas with little or no *Leishmania infantum.*

How does CaniLeish work?

CaniLeish is a vaccine that contains a number of proteins that are released from the *Leishmania infantum* parasite during its growth.

CaniLeish is a vaccine. Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against a disease. When CaniLeish is given to dogs the immune system recognises the proteins as 'foreign' and make defences against it. In the future, if the animals are exposed to *Leishmania infantum* parasite, the immune system will be able to respond more quickly. This will help to protect against the disease.

CaniLeish contains an 'adjuvant' (a highly purified fraction of *Quillaja saponaria*) to enhance the immune response.

How has CaniLeish been studied?

The safety of the vaccine was studied in two main laboratory safety studies carried out in leishmania-free dogs (overdose and single and repeated administration) and one field trial. The vaccine was generally well tolerated as shown by the absence of major adverse reactions.

The efficacy of the vaccine was studied in one main field trial that lasted for two years involving vaccinated and control dogs submitted to natural exposure to infection in zones where there is a high risk of infection. A number of laboratory trials where dogs were submitted to experimental infection were also presented.

What benefit has CaniLeish shown during the studies?

The studies showed that the vaccine is safe for both leishmania-negative and leishmania-infected dogs. The benefit of the vaccination was assessed in zones with a high risk of infection where it has been shown in leishmania free dogs to decrease the risk of developing an active infection and a symptomatic disease after contact with the parasite. The number of dogs developing an active infection and a symptomatic disease was significantly reduced in the vaccinated group.

The efficacy of vaccination in dogs already infected was not investigated and therefore cannot be recommended. In dogs developing leishmaniosis (active infection or disease) despite vaccination, proceeding with vaccine injections showed no benefit.

The risk of vaccine-induced infection can be excluded since the vaccine does not contain parasites.

What is the risk associated with CaniLeish?

After injection, some dogs can have moderate and temporary local reactions, such as swelling, nodule (hardening), pain on palpation or erythema (reddening). These reactions resolve spontaneously within two days to two weeks. Other temporary signs commonly seen following vaccination can also occur such as hyperthermia (raised body temperature), apathy (lack of vitality) and digestive disorders lasting one to six days. Allergic-type reactions are uncommon and if a dog shows signs of an allergic reaction, they should be given appropriate symptomatic treatment.

After vaccination transient antibodies against leishmania detected by immunofluorescence antibody test (IFAT) may appear but do not reflect an active infection.

What are the precautions for the person who gives the medicine or comes into contact with the animal?

In case of accidental self-injection, the advice of a doctor should be sought immediately.

Why has CaniLeish been approved?

The CVMP concluded that the benefits of CaniLeish outweigh the risks for the active immunisation of leishmania-negative dogs from six months of age to reduce the risk to develop an active infection and clinical disease after contact with *Leishmania infantum* and recommended that CaniLeish be given a marketing authorisation. The benefit-risk balance may be found in the scientific discussion module of this EPAR.

Other information about CaniLeish:

The European Commission granted a marketing authorisation valid throughout the European Union, for CaniLeish to Virbac S.A. on 14/03/2011. Information on the prescription status of this product may be found on the label/outer package.

This summary was last updated on 14/03/2011.