



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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EPAR summary for the public

Letifend

canine leishmaniasis vaccine (recombinant protein)

This is a summary of the European public assessment report (EPAR) for Letifend. It explains how the Agency assessed this veterinary medicine to recommend its authorisation in the European Union (EU) and its conditions of use. It is not intended to provide practical advice on how to use Letifend.

For practical information about using Letifend, animal owners or keepers should read the package leaflet or contact their veterinarian or pharmacist.

What is Letifend and what is it used for?

Letifend is a veterinary vaccine used in dogs to protect them against leishmaniasis due to the parasite *Leishmania infantum*. The parasite is widespread in countries bordering the Mediterranean Sea and is transmitted by the bites of sand flies. Dogs that have been infected may show no signs of infection, but some have active disease with symptoms such as fever, hair and weight loss, and skin sores. Infected dogs can help spread the disease to humans.

Letifend contains the active substance protein Q, which is made of different fragments of proteins from *Leishmania infantum*.

For further information, see the package leaflet.

How is Letifend used?

Letifend is available as a freeze-dried powder (lyophilisate) and solvent that are made up into a solution for injection, and can only be obtained with a prescription.

Before vaccination, dogs should be tested for *Leishmania* infection. Only non-infected animals should be vaccinated.

The vaccine is given to dogs from 6 months of age as a single injection under the skin. A 'booster' injection should be given every year to maintain the vaccine's effect. Protection starts four weeks after vaccination and lasts one year. Measures should be taken to reduce exposure to sand flies in



vaccinated dogs since the vaccine does not prevent *Leishmania* infection.

For further information, see the package leaflet.

How does Letifend work?

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

What benefits of Letifend have been shown in studies?

In a field study in France and Spain 275 dogs were vaccinated with Letifend and 274 dogs received placebo (a dummy vaccination). The dogs were exposed to natural infection with *Leishmania infantum*. Over a two year period there were 8 confirmed cases of leishmaniasis in the vaccinated group compared with 19 cases in the placebo group, showing that Letifend was effective in reducing the occurrence of the disease.

What are the risks associated with Letifend?

The most common side effect with Letifend (which may affect more than 1 in 10 animals) is scratching at the injection site which resolves within four hours.

For the full list of restrictions, see the package leaflet.

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

None.

Why is Letifend approved?

The Agency's Committee for Medicinal Products for Veterinary Use (CVMP) concluded that Letifend's benefits are greater than its risks and recommended that it be approved for use in the EU.

Other information about Letifend?

The European Commission granted a marketing authorisation valid throughout the EU for Letifend on 20.04.2016.

The full EPAR for Letifend can be found on the Agency's website: ema.europa.eu/Find_medicine/Veterinary_medicines/European_public_assessment_reports. For more information about treatment with Letifend, animal owners or keepers should read the package leaflet or contact their veterinarian or pharmacist.

This summary was last updated in February 2016.