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## EPAR summary for the public

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# Versican Plus L4

## Canine leptospirosis vaccine (inactivated)

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 Versican Plus L4?

Versican Plus L4 is a veterinary vaccine that contains inactivated (killed) strains of *Leptospira* bacteria (Icterohaemorrhagiae, Canicola, Bratislava and Grippotyphosa). Versican Plus L4 is available as a suspension for injection.

### What is Versican Plus L4 used for?

Versican Plus L4 is used to protect dogs against leptospirosis, a bacterial disease that may be transmitted via infected urine and result in bleeding, hepatitis (inflammation of the liver) and jaundice or nephritis (kidney inflammation).

The vaccine is given to puppies from six weeks of age as an injection, under the skin, and repeated three to four weeks later. For revaccination a single dose of Versican Plus L4 is required annually.

### How does Versican Plus L4 work?

Versican Plus L4 is a vaccine. Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against a disease. The strains of *Leptospira* bacteria in Versican Plus L4 are killed (inactivated) so that they do not cause disease. When Versican Plus L4 is given to dogs the animals' immune system recognises the bacteria as 'foreign' and makes antibodies against them. In



the future, if the animals are exposed to these *Leptospira* bacteria the immune system will be able to respond more quickly. This will help protect them against leptospirosis.

Versican Plus L4 contains an adjuvant (aluminium hydroxide) to enhance the immune response.

### **How has Versican Plus L4 been studied?**

The effectiveness of Versican Plus L4 was investigated in a field study involving 129 dogs. The dogs were either vaccinated twice with a three or four week interval or they received a single annual booster vaccination. The measure of effectiveness was levels of antibodies before and after vaccination.

### **What benefit has Versican Plus L4 shown during the studies?**

The field study showed that after vaccination with Versican Plus L4 the percentage of dogs with protective levels of antibodies for leptospira ranged from 59 to 96%. Responses in puppies were lower than adult dogs in some cases, because of antibodies inherited from their mothers.

### **What is the risk associated with Versican Plus L4?**

The most common side effect (seen in more than 1 in 100 dogs) with Versican Plus L4 is a short lived swelling of up to 5 cm which may occur at the injection site after vaccination.

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

In case of accidental self-injection, medical advice should be sought immediately and the package leaflet or label shown to the doctor.

### **Why has Versican Plus L4 been approved?**

The Committee for Medicinal Products for Veterinary Use (CVMP) concluded that the benefits of Versican Plus L4 exceed the risks for the approved indication and recommended that Versican Plus L4 be given a marketing authorisation. The benefit-risk balance may be found in the scientific discussion module of this EPAR.

### **Other information about Versican Plus L4:**

The European Commission granted a marketing authorisation valid throughout the European Union, for Versican Plus L4 on 31 July 2014. Information on the prescription status of this product may be found on the label/outer package.

This summary was last updated in June 2014.