



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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## EPAR summary for the public

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### Versican Plus Pi/L4R

Canine parainfluenza virus (live attenuated), canine leptospirosis and rabies (inactivated) vaccine

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 Pi/L4R?

Versican Plus Pi/L4R is a veterinary vaccine that contains live attenuated (weakened) canine parainfluenza virus type 2, inactivated (killed) strains of *Leptospira* bacteria (Icterohaemorrhagiae, Canicola, Bratislava and Grippotyphosa) as well as rabies virus. Versican Plus Pi/L4R is available as a lyophilisate (freeze-dried pellet) with solvent for injection.

#### What is Versican Plus Pi/L4R used for?

Versican Plus Pi/L4R is used to protect dogs against:

- canine parainfluenza virus, which causes kennel cough;
- 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);
- rabies, a viral zoonotic (communicable to man) disease that affects the central nervous system (brain and spinal cord), leading to death. It is typically transmitted through bites of infected animals.



The vaccine is given to puppies from eight to nine weeks of age as an injection, under the skin, and repeated once the puppies reach twelve weeks of age. For revaccination a single dose of Versican Plus Pi/L4R is required annually.

### **How does Versican Plus Pi/L4R work?**

Versican Plus Pi/L4R is a vaccine. Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against a disease. The canine parainfluenza virus in Versican Plus Pi/L4R is alive but has been attenuated (weakened) so that it does not cause disease; it is combined with killed (inactivated) strains of *Leptospira* bacteria and rabies virus. When Versican Plus Pi/L4R is given to dogs the animals' immune system recognises the viruses and bacteria as 'foreign' and makes antibodies against them. In the future, if the animals are exposed to these infections the immune system will be able to respond more quickly. This will help protect them against kennel cough, leptospirosis and rabies.

Versican Plus Pi/L4R contains an adjuvant (aluminium hydroxide) to enhance the immune response.

### **How has Versican Plus Pi/L4R been studied?**

The effectiveness of Versican Plus Pi/L4R 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 Pi/L4R shown during the studies?**

The field study showed that after vaccination with Versican Plus Pi/L4R the percentage of dogs with protective levels of antibodies for parainfluenza virus ranged from 73 to 97%, for leptospira 59 to 96% and for rabies virus 86 to 100%. 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 Pi/L4R?**

The most common side effect (seen in more than 1 in 100 dogs) with Versican Plus Pi/L4R is a short lived swelling of up to 5 cm which may occur at the injection site after vaccination.

In situations where puppies are expected to inherit very high antibody levels from the bitch the vaccination protocol should be planned accordingly.

### **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 Pi/L4R been approved?**

The Committee for Medicinal Products for Veterinary Use (CVMP) concluded that the benefits of Versican Plus Pi/L4R exceed the risks for the approved indications and recommended that Versican Plus Pi/L4R 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 Pi/L4R:**

The European Commission granted a marketing authorisation valid throughout the European Union, for Versican Plus Pi/L4R 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.