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EPAR summary for the public

Versican Plus DHPPi/L4R

Canine distemper, adenovirus, parvovirus, parainfluenza virus (live attenuated), canine leptospirosis, 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 DHPPi/L4R?

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

What is Versican Plus DHPPi/L4R used for?

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

- canine distemper, an infectious disease which is sometimes called hard pad since dogs can develop thickening of the skin on the foot pads, as well as runny nose, cough, fever, vomiting and diarrhoea, excessive salivation and in some cases fits;
- canine adenovirus, which causes an acute liver infection that may produce signs of jaundice (yellowing of the skin and eyes);
- canine parvovirus disease, an infection that may severely affect puppies, resulting in lethargy, fever, vomiting and bloody diarrhoea;
- canine parainfluenza virus, the cause of 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 DHPPI/L4R is required every three years for distemper, canine adenovirus (type 1 and 2) and parvovirus. Annual revaccination is required for protection against parainfluenza virus, leptospirosis and rabies.

How does Versican Plus DHPPI/L4R work?

Versican Plus DHPPI/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 distemper virus, canine adenovirus, canine parvovirus and canine parainfluenza virus in Versican Plus DHPPI/L4R are alive but they have been attenuated (weakened) so that they do not cause disease; they are combined with killed (inactivated) strains of *Leptospira* bacteria and rabies virus. When Versican Plus DHPPI/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 distemper, adenovirus, parvovirus, kennel cough, leptospirosis and rabies.

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

How has Versican Plus DHPPI/L4R been studied?

The effectiveness of Versican Plus DHPPI/L4R was initially 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.

Laboratory studies were conducted subsequently to determine the period of protection against distemper, canine adenovirus (type 1 and 2) and parvovirus. In these studies dogs were vaccinated twice with a three week interval and were challenged with canine distemper virus, canine adenovirus and canine parvovirus three years after the second vaccination. The measures of effectiveness were clinical signs, body temperature and level of antibodies.

What benefit has Versican Plus DHPPI/L4R shown during the studies?

The field study showed that vaccination with Versican Plus DHPPI/L4R resulted in levels of antibodies that were sufficient to protect against canine distemper virus and canine adenovirus in all dogs. The percentage of dogs with protective levels of antibodies for parvovirus ranged from 73 to 100%, for parainfluenza virus 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.

The laboratory studies showed the period of protection to be three years for canine distemper, canine adenovirus and canine parvovirus.

What is the risk associated with Versican Plus DHPPI/L4R?

The most common side effect (seen in more than 1 in 100 dogs) with Versican Plus DHPPI/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 DHPPI/L4R been approved?

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

The European Commission granted a marketing authorisation valid throughout the European Union, for Versican Plus DHPPI/L4R on 7 May 2014. Information on the prescription status of this product may be found on the label/outer package.

This summary was last updated in March 2015.