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EPAR summary for the public

Versican Plus DHPPi/L4

Canine distemper, canine adenovirus, canine parvovirus, canine parainfluenza virus (live attenuated) and canine leptospirosis (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/L4?

Versican Plus DHPPi/L4 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. Versican Plus DHPPi/L4 is available as a lyophilisate (freeze-dried pellet) with a solvent for injection.

What is Versican Plus DHPPi/L4 used for?

Versican Plus DHPPi/L4 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, diarrhoea, excessive salivation and in some cases fits;
- canine adenovirus type 1, 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 and canine adenovirus type 2, which cause kennel cough;
- leptospirosis, a bacterial disease that may be transmitted via infected urine and results 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, repeated three to four weeks later. For revaccination, a single dose of Versican Plus DHPPI/L4 is required every three years for distemper, canine adenovirus (type 1 and type 2) and parvovirus. Annual revaccination is required for protection against parainfluenza virus and leptospirosis.

How does Versican Plus DHPPI/L4 work?

Versican Plus DHPPI/L4 is a vaccine. Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against a disease. The viruses in Versican Plus DHPPI/L4 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. When Versican Plus DHPPI/L4 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 liver infection, parvovirus, kennel cough and leptospirosis.

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

How has Versican Plus DHPPI/L4 been studied?

The effectiveness of Versican Plus DHPPI/L4 was initially investigated in a field study involving 129 dogs. The dogs were either vaccinated twice with a three to 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/L4 shown during the studies?

The field study showed that vaccination with Versican Plus DHPPI/L4 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% and for leptospira 59 to 96%. Responses in puppies were lower than in 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/L4?

The most common side effect (seen in more than 1 in 100 dogs) with Versican Plus DHPPI/L4 is a shortlived 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/L4 been approved?

The Committee for Medicinal Products for Veterinary Use (CVMP) concluded that the benefits of Versican Plus DHPPI/L4 exceed the risks for the approved indications and recommended that Versican Plus DHPPI/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 DHPPI/L4:

The European Commission granted a marketing authorisation valid throughout the European Union, for Versican Plus DHPPI/L4 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.