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EPAR summary for the public

Nobivac L4

Leptospira 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 Nobivac L4?

Nobivac L4 is a vaccine available as a suspension for injection. It contains four inactivated (killed) strains of Leptospira bacteria.[1].

What is Nobivac L4 used for?

Nobivac L4 is used to vaccinate dogs from six weeks of age to reduce the risk of developing an infection with certain Leptospira strains. Leptospirosis disease in dogs results in bleeding, hepatitis (infection of the liver) and jaundice (yellowing of the skin and eyes) or nephritis (kidney infection). The main infection source is from urine or urine-contaminated water or soil. The vaccine also reduces the excretion (shedding) of the virus into the urine by the infected dogs, thereby reducing the risk of transmission.

The vaccine is given to dogs as two injections, four weeks apart, under the skin. The first injection can be given from six to nine weeks of age and the second four weeks later. When puppies are known to have high levels of maternally derived antibodies (special type of proteins, received from the mother in the milk, that help the body to fight infection), it is recommended that the first vaccination is given at

[1] *L. interrogans* serogroup Canicola serovar Portland-vere (strain Ca-12-000), *L interrogans* serogroup Icterohaemorrhagiae serovar Copenhageni (strain Ic-02-001), *L. interrogans* serogroup Australis serovar Bartislava (strain As-05-073), *L. kirscheneri* serogrop Grippotyphosa serovar Dadas (strain Gr-01-005)).

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nine weeks of age. A single 'booster' injection should be given every year to maintain the vaccine's effect.

How does Nobivac L4 work?

Nobivac L4 is a vaccine. Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against a disease. When Nobivac L4 is given to dogs, the immune system recognises the bacteria contained in the vaccine as 'foreign' and makes defences against them. In future if the animals are exposed to the bacteria the immune system will be able to respond more quickly. This will help to protect against the disease.

How has Nobivac L4 been studied?

The company has presented data from both laboratory and field studies to establish the safety and effectiveness of the vaccine, including how long it took for the dogs to be fully protected and how long the vaccine could provide protection.

What benefit has Nobivac L4 shown during the studies?

The studies showed that the vaccine reduces infection with Leptospira and excretion of the bacteria into the urine. They also showed that the vaccine is safe to give to pregnant bitches.

What is the risk associated with Nobivac L4?

A mild and temporary increase in body temperature (≤ 1°C) may occur for a few days after vaccination, with some puppies showing less activity and/or a reduced appetite. A small, temporary swelling may occur at the injection site, which will either disappear or reduce in size within two weeks after vaccination. An occasional temporary, acute (short-term) hypersensitivity (allergic) reaction may occur.

Why has Nobivac L4 been approved?

The Committee for Medicinal Products for Veterinary Use (CVMP) concluded that the benefits of Nobivac L4 exceed the risks and recommended that it be given a marketing authorisation. The benefit/risk balance can be found in the scientific discussion module of this EPAR.

Other information about Nobivac L4:

The European Commission granted a marketing authorisation valid throughout the European Union, for Nobivac L4 on 16 July 2012. Information on the prescription status of this product may be found on the label/outer package.

This summary was last updated on 16 July 2012.