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EPAR summary for the public

Nobivac Myxo-RHD

Live myxoma vectored RHD virus strain 009

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 Myxo-RHD?

Nobivac Myxo-RHD is a vaccine that contains live myxoma vectored RHD virus strain 009. It is available as a lyophilisate (freeze-dried substance) and a solvent that are made up into a suspension for injection.

What is Nobivac Myxo-RHD used for?

Nobivac Myxo-RHD is used in rabbits aged five weeks or more to reduce number of deaths and clinical signs due to myxomatosis (skin tumours caused by the myxoma virus) and to prevent death due to rabbit haemorrhagic disease (RHD), a disease resulting in blood clot formation caused by the RHD virus.

How does Nobivac Myxo-RHD work?

Nobivac Myxo-RHD, like all vaccines, works by 'teaching' the immune system (the body's natural defence) how to defend itself against a disease. It contains a weakened strain of the myxoma virus which has been genetically modified so that it can produce a protein of the RHD virus. When it is given to rabbits the immune system recognises the myxoma and RHD materials as 'foreign' and makes antibodies against them. In the future, if the rabbits are exposed to any of the viruses, the immune system will be able to respond more quickly. This will help to protect against the diseases.



How has Nobivac Myxo-RHD been studied?

Fifteen field and laboratory studies were carried out, in which rabbits vaccinated with Nobivac Myxo-RHD were compared with unvaccinated rabbits to establish the onset and duration of immunity against myxoma and RHD viruses.

What benefit has Nobivac Myxo-RHD shown during the studies?

The studies showed that Nobivac Myxo-RHD was effective in providing immunity against myxomatosis and RHD three weeks after vaccination and that the immunity was still present after one year. Rabbits that were vaccinated with Nobivac Myxo-RHD had fewer signs of myxomatosis, more antibodies against RHD virus in their blood and a lower death rate than unvaccinated rabbits.

What is the risk associated with Nobivac Myxo-RHD?

A temporary increase in body temperature of 1-2°C can occur. There may also be a small, painless swelling at the injection site within the first two weeks after vaccination. The swelling will resolve completely by the end of the third week.

What is the withdrawal period?

The withdrawal period is the time allowed after administration of the medicine and before the animal can be slaughtered and the meat used for human consumption. The withdrawal period for Nobivac Myxo-RHD is zero days.

Why has Nobivac Myxo-RHD been approved?

The Committee for Medicinal Products for Veterinary Use (CVMP) concluded that the benefits of Nobivac Myxo-RHD exceed the risks when used to reduce the number of deaths and clinical signs due to myxomatosis and prevent death due to rabbit haemorrhagic disease. The Committee recommended that Nobivac Myxo-RHD be given a marketing authorisation. The benefit-risk balance may be found in the scientific discussion module of this EPAR.

Other information about Nobivac Myxo-RHD:

The European Commission granted a marketing authorisation valid throughout the European Union, for Nobivac Myxo-RHD to Intervet International BV on 7 September 2011. Information on the prescription status of this product may be found on the label/outer package.

This summary was last updated on 7 September 2011.