



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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## Nobivac Myxo-RHD Plus (*myxomatosis and rabbit haemorrhagic disease vaccine, recombinant live*)

An overview of Nobivac Myxo-RHD Plus and why it is authorised in the EU

### What is Nobivac Myxo-RHD Plus and what is it used for?

Nobivac Myxo-RHD Plus is a vaccine used in rabbits to reduce death and clinical signs due to myxomatosis and rabbit haemorrhagic disease (RHD). Myxomatosis is caused by the myxoma virus and is spread between rabbits by close contact and biting insects such as fleas and mosquitoes. The virus causes swelling and discharge from the eyes, nose and bottom with most rabbits dying within 10 – 14 days. RHD, caused by classical RHD virus (RHDV1) and RHD type 2 virus (RHDV2), leads to blood clots in major organs such as the heart, lungs and kidneys leading to heart and respiratory failure when the heart and lungs do not work properly. Nobivac Myxo-RHD Plus contains live myxoma vectored RHD virus strains 009 and MK1899.

### How is Nobivac Myxo-RHD Plus used?

Nobivac Myxo-RHD Plus is available as a freeze dried powder (lyophilisate) and solvent for suspension for injection and can only be obtained with a prescription. It is given to rabbits from five weeks of age as a single injection under the skin. Protection starts at three weeks and lasts for one year. Rabbits need to be revaccinated every year.

For more information about using Nobivac Myxo-RHD Plus, see the package leaflet or contact your veterinarian or pharmacist.

### How does Nobivac Myxo-RHD Plus work?

Nobivac Myxo-RHD Plus is a vaccine. Vaccines work by preparing the immune system (the body's natural defences) to defend itself against a specific disease. Nobivac Myxo-RHD Plus contains small amounts of weakened forms of the myxoma virus that causes myxomatosis. These viruses have been modified so that they also produce proteins from the outer coat of either RHDV1 (strain 009) or RHDV2 (strain MK1899). When a rabbit is given the vaccine, the immune system recognises the weakened viruses in the vaccine as 'foreign' and makes antibodies against both the myxoma virus and the RHD virus proteins. When the rabbit comes into contact with these or similar viruses, these antibodies,

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together with other components of the immune system, will be able to kill the viruses and help protect against the diseases.

### **What benefits of Nobivac Myxo-RHD Plus have been shown in studies?**

Four laboratory studies were conducted in young rabbits that showed protection began three weeks after vaccination and lasted 12 months against RHDV1 and RHDV2. For myxoma virus, rabbits were tested for antibodies only. Antibody levels increased for up to six weeks following vaccination and stayed at this level for 12 months. In addition, the company also presented field studies with the already authorised vaccine Nobivac Myxo-RHD which contains live myxoma vectored RHD virus strain 009 only. These studies showed that rabbits that were vaccinated with Nobivac Myxo-RHD had fewer signs of myxomatosis, more antibodies against RHDV1 virus in their blood and a lower death rate than unvaccinated rabbits.

### **What are the risks associated with Nobivac Myxo-RHD Plus?**

The most common side effects with Nobivac Myxo-RHD Plus (which may affect up to 1 in 10 animals) are a short-lived temperature increase of 1 to 2 °C and a small, non-painful swelling (maximum 2 cm diameter) at the injection site within the first two weeks after vaccination. The swelling resolves completely by 3 weeks after vaccination.

For the full list of side effects and restrictions for Nobivac Myxo-RHD Plus, see the package leaflet.

### **What are the precautions for the person who gives the medicine or comes into contact with the animal?**

No special precautions are required.

### **What is the withdrawal period in food-producing animals?**

The withdrawal period is the time required after administration of a medicine before an animal can be slaughtered and the meat used for human consumption.

The withdrawal period for meat from rabbits treated with Nobivac Myxo-RHD Plus is 'zero' days, which means that there is no mandatory waiting time.

### **Why is Nobivac Myxo-RHD Plus authorised in the EU?**

The European Medicines Agency decided that Nobivac Myxo-RHD Plus's benefits are greater than its risks and it can be authorised for use in the EU.

### **Other information about Nobivac Myxo-RHD Plus**

Nobivac Myxo-RHD Plus received a marketing authorisation valid throughout the EU on 19 November 2019.

Further information on Nobivac Myxo-RHD Plus can be found on the Agency's website: [ema.europa.eu/medicines/veterinary/EPAR/nobivac-myxo-rhd-plus](http://ema.europa.eu/medicines/veterinary/EPAR/nobivac-myxo-rhd-plus).

This overview was last updated in September 2019.