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Fatrovax RHD (*rabbit haemorrhagic disease vaccine [inactivated, recombinant]*)

An overview of Fatrovax RHD and why it is authorised in the EU

What is Fatrovax RHD and what is it used for?

Fatrovax RHD is a veterinary vaccine used to reduce mortality and signs of rabbit haemorrhagic disease (RHD). It contains two VLPs (virus-like particles) formed from proteins that are part of the 'envelope' of the viruses that cause the disease: one from rabbit haemorrhagic disease virus 1 (RHDV1) and one from rabbit haemorrhagic disease virus 2 (RHDV2).

How is Fatrovax RHD used?

Fatrovax RHD is a suspension for injection to be given subcutaneously (under the skin); the recommended dose is 0.5 ml, to be given at 28 days of age. Protection starts seven days after vaccination and lasts for one year. For continued protection, revaccination is required every year. The vaccine can only be obtained with a prescription.

For more information about using Fatrovax RHD, see the package leaflet or contact your veterinarian or pharmacist.

How does Fatrovax RHD work?

Fatrovax RHD is a vaccine. Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against a disease. Fatrovax RHD contains inactivated proteins of the two viruses that cause rabbit haemorrhagic disease. These proteins cannot cause disease. When Fatrovax RHD is given to rabbits, the animals' immune system recognises the inactivated proteins as 'foreign' and makes antibodies against them. These antibodies help the rabbits to fight infection if they become exposed to the virus.

What benefits of Fatrovax RHD have been shown in studies?

Laboratory studies were conducted that showed Fatrovax RHD's effectiveness.

Two studies showed that Fatrovax RHD provided protection from one week after vaccination. The efficacy against challenge infection with RHDV2 was determined in 24 rabbits. Half the rabbits were vaccinated and half received a placebo (dummy) injection. One week later, RHDV2 was given by

injection under the skin. Survival rate was 100% for the vaccinated group and 0% for the placebo group. Efficacy against challenge infection with RHDV1 was determined in 34 rabbits. Rabbits were vaccinated at 30 days of age or at 51 days of age or were given placebo before injection with RHDV1 one week later. Survival rate was 100% for the group vaccinated at 30 days, 91.6% for the group vaccinated at 51 days and 10% for the group given placebo.

Two studies were performed which showed that Fatrovax RHD provided protection 6 months and 12 months after vaccination. In the first study, 30 rabbits were vaccinated and 16 were unvaccinated. After 6 months, the rabbits were injected with RHDV2. All of the unvaccinated rabbits died within 48 hours of infection. All but one of the vaccinated rabbits survived without showing any notable clinical signs of the disease. In the second study, similar results were seen at 12 months after challenge infection with RHDV1 and RHDV2.

What are the risks associated with Fatrovax RHD?

The most common side effect with Fatrovax RHD (which may affect more than 1 but less than 10 animals in 100 animals treated) is a very small transient nodule (maximum 5.2 mm diameter) at the site of injection in the first week post vaccination.

For the full list of side effects and restrictions of Fatrovax RHD, see the package leaflet.

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

Safety information has been included in the summary of product characteristics and the package leaflet for Fatrovax RHD, including the appropriate precautions to be followed by healthcare professionals and animal owners or keepers.

In case of accidental self-injection, medical advice should be sought immediately and the package leaflet or label shown to the doctor.

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 Fatrovax RHD is 'zero' days, which means that there is no mandatory waiting time.

Why is Fatrovax RHD authorised in the EU?

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

Other information about Fatrovax RHD

Fatrovax RHD received a marketing authorisation valid throughout the EU on 16 August 2021.

Further information on Fatrovax RHD can be found on the Agency's website: ema.europa.eu/medicines/veterinary/EPAR/fatrovax-rhd.

This overview was last updated in 08-2021.