EMA/563874/2016
EMEA/V/C/004239

Eravac (*rabbit haemorrhagic disease vaccine, inactivated*)

An overview of Eravac and why it is authorised in the EU

What is Eravac and what is it used for?

Eravac is a veterinary vaccine used in rabbits to reduce death due to the rabbit haemorrhagic disease (RHD), caused by the variant of RHD virus called RHD type 2 (RHDV2). It is usually a fatal disease resulting in the formation of blood clots.

RHD type 2 virus differs from the classic form of RHD virus since the course of disease is more prolonged, death occurs later and over a longer period and is more severe in young rabbits.

Eravac contains inactivated rabbit haemorrhagic disease type 2 virus, strain V-1037, as the active substance.

How is Eravac used?

Eravac is available as an injection and can only be obtained with a prescription. The vaccine is given to rabbits from 30 days of age as a single injection under the skin of the side of the chest. Protection starts one week after vaccination and lasts 12 months. Rabbits should be revaccinated one year after vaccination.

For further information, see the package leaflet.

How does Eravac work?

Eravac is a vaccine. Vaccines work by preparing the immune system (the body's natural defences) to defend itself against a specific disease. Eravac contains rabbit haemorrhagic disease type 2 virus (RHDV2) strain V-1037, which has been inactivated so it cannot cause the disease. When it is given to rabbits, the immune system recognises the virus in the vaccine as 'foreign' and makes antibodies against it. In the future if rabbits come into contact with rabbit haemorrhagic disease type 2 virus, these antibodies, together with other components of the immune system, will be able to destroy the virus and help protect against the disease.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Eravac contains an adjuvant (mineral oil) to enhance the immune response.

What benefits of Eravac have been shown in studies?

The effectiveness of the vaccine was initially compared with that of a placebo (dummy) vaccine in three laboratory studies involving 301 rabbits. After vaccination the rabbits were artificially infected with RHDV2. The studies showed the vaccine to be effective in reducing death. In one study all Eravac-vaccinated rabbits survived, compared with a 37% survival rate in the group that received the placebo vaccine. In the second study survival of Eravac-vaccinated rabbits was 93% compared with 50% for rabbits given placebo. In the third study all Eravac-vaccinated rabbits survived, compared with less than 70% of the rabbits in the control group, when rabbits were artificially infected with RHDV2 nine months after vaccination.

In a later laboratory study involving 48 rabbits, 95% of Eravac vaccinated rabbits survived, compared to 65% of rabbits given placebo, following artificial infection with RHDV2 at 12 months after vaccination.

What are the risks associated with Eravac?

The most common side effects with Eravac (which may affect more than 1 in 10 rabbits) are a short-lived increase in body temperature to slightly above 40 ºC, which may occur between two or three days after vaccination, and nodules or swellings (less than 2 cm in size) at the injection site. The slight temperature increase resolves spontaneously without treatment within 5 days and the local reactions resolve spontaneously within 24 hours.

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

Accidental injection may cause severe pain and swelling, particularly if injected into a joint or finger – this could result in the loss of the finger if prompt medical attention is not given. If someone is accidentally injected with this product, they must seek medical attention immediately even if only a very small amount is injected. The package leaflet should be shown to the doctor. If pain persists for more than 12 hours after medical examination, the doctor should be contacted again.

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 Eravac for is ‘zero’ days, which means there is no mandatory waiting time.

Why is Eravac approved in the EU?

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

Other information about Eravac?

Eravac received a marketing authorisation valid throughout the EU for Eravac on 22 September 2016.

Further information on Eravac can be found on the Agency's website: ema.europa.eu/medicines/veterinary/EPAR/eravac.

This summary was last updated in December 2019.