



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Prevexxion RN+HVT+IBD (*Marek's disease vaccine, live recombinant*)

An overview of Prevexxion RN+HVT+IBD and why it is authorised in the EU

What is Prevexxion RN+HVT+IBD and what is it used for?

Prevexxion RN+HVT+IBD is a veterinary vaccine used in one-day-old chicks to prevent death and disease and to reduce lesions caused by Marek's disease (MD) virus (including very virulent MD virus); It is also used to prevent death, disease and lesions caused by infectious bursal disease (IBD, also known as Gumboro disease) virus.

MD is a herpesvirus infection of chickens which can cause paralysis of the wings and legs and causes tumours in various organs. Chickens become infected at an early age via inhalation of dander (flakes of skin) containing the virus which can remain infectious for several months after being shed from the body. Birds infected with MD virus can be carriers and shedders of the virus for life.

IBD is a highly contagious viral infection of young chickens that reduces their immunity (body's ability to fight disease) and can lead to their death at 3 to 6 weeks of age. Signs of chickens infected with the disease include trembling, ruffled feathers, poor appetite, dehydration, diarrhoea and huddling.

Prevexxion RN+HVT+IBD contains cells with both a live modified strain of MD virus, serotype 1 called RN1250 that has been modified to increase its effectiveness and safety and a live modified strain of turkey herpesvirus called vHVT013-69 that has been modified to produce a protein from IBD virus.

How is Prevexxion RN+HVT+IBD used?

Prevexxion RN+HVT+IBD is available as a concentrate and solvent to be made into a suspension for injection and can only be obtained with a prescription.

The vaccine can be given to one-day-old chicks as a single injection under the skin in the neck. Protection against MD starts 5 days after vaccination and lasts for life. Protection against IBD starts 14 days after vaccination and lasts for 10 weeks after vaccination.

For more information about using Prevexxion RN+HVT+IBD, see the package leaflet or contact your veterinarian or pharmacist.

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How does Prevexxion RN+HVT+IBD work?

Prevexxion RN+HVT+IBD is a vaccine. Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against a disease. Prevexxion RN+HVT+IBD contains modified MD virus and modified turkey herpesvirus which do not cause disease in chickens but are similar to the virus that causes MD. The turkey herpesvirus has been modified so that it also makes a protein from IBD virus. When Prevexxion RN+HVT+IBD is given to chickens, their immune system recognises the viruses as 'foreign' and makes antibodies against their proteins. In the future if the animals are exposed to similar proteins, the immune system will be able to respond more quickly. This will help protect the chickens against MD and IBD.

What benefits of Prevexxion RN+HVT+IBD have been shown in studies?

Prevexxion RN+HVT+IBD was investigated in 8 laboratory studies and 2 field studies.

The studies showed that Prevexxion RN+HVT+IBD prevents death and clinical signs of MD and reduces lesions caused by MD virus, including very virulent MD virus. Data from studies indicate that birds are protected against MD from the 5th day after vaccination and the protection lasts for life.

For IBD, studies showed that vaccination with Prevexxion RN+HVT+IBD provides full protection against death and signs of disease caused by IBD virus. The birds were protected from the 14th day after vaccination and the protection lasted for 10 weeks. The start of protection against IBD may be delayed in chickens with maternally-derived antibodies against MD.

What are the risks associated with Prevexxion RN+HVT+IBD?

Since Prevexxion RN+HVT+IBD is a live vaccine, both vaccine strains may be passed into the environment from vaccinated chickens. The RN1250 strain has not been shown to spread under laboratory conditions. The vHVT013-69 strain may spread to unvaccinated chickens and turkeys. Precautionary measures must be followed to avoid spread of the vaccine strains to unvaccinated chickens, turkeys and other susceptible species.

There are no known side effects when used at the recommended dose. For the full list of restrictions, 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 Prevexxion RN+HVT+IBD, including the appropriate precautions to be followed by healthcare professionals and animal owners or keepers.

As the vaccine is stored in liquid nitrogen, it is important that any handling is done in a well-ventilated area and that precautions are taken when preparing the vaccine. For further information see the summary of product characteristics.

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. It is also the time required after administration of a medicine before eggs may be used for human consumption.

The withdrawal period for meat and eggs from chickens treated with Prevexxion RN+HVT+IBD is 'zero' days, which means there is no mandatory waiting time.

Why is Prevexxion RN+HVT+IBD authorised in the EU?

Prevexxion RN+HVT+IBD has been shown to prevent death and signs of Marek's disease and infectious bursal disease in vaccinated chickens. There is no evidence that the vaccine harms chickens or the environment. The European Medicines Agency decided that Prevexxion RN+HVT+IBD's benefits are greater than its risks and it can be authorised for use in the EU.

Other information about Prevexxion RN+HVT+IBD

Prevexxion RN+HVT+IBD received a marketing authorisation valid throughout the EU on 20 July 2020.

Further information on Prevexxion RN+HVT+IBD can be found on the Agency's website: ema.europa.eu/medicines/veterinary/EPAR/prevexxion-rn-hvt-ibd.

This overview was last updated in 03-2021.