



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/CVMP/367209/2020
EMA/V/C/005190

Innovax-ND-ILT (*Marek's disease vaccine, Newcastle disease vaccine and infectious laryngotracheitis vaccine (live recombinant)*)

An overview of Innovax-ND-ILT and why it is authorised in the EU

What is Innovax-ND-ILT and what is it used for?

Innovax-ND-ILT is a veterinary vaccine used to protect chickens against three separate infections, caused by Newcastle disease (ND) virus, avian infectious laryngotracheitis (ILT) virus and Marek's disease (MD) virus.

ND is a viral infection of chickens which causes gasping and coughing, nervous signs (drooping wings, twisting of the head and neck, circling and paralysis), swelling of the tissues around the eyes and neck, greenish watery diarrhoea and reduced egg production.

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.

ILT virus infections can produce respiratory signs, decreased egg production, thin egg shells, lack of growth, neurological and ophthalmologic signs and death.

Innovax-ND-ILT contains a live strain of turkey herpesvirus (strain HVT) which has been modified so that it will produce proteins from ND virus and ILT virus.

How is Innovax-ND-ILT used?

Innovax-ND-ILT is available as a concentrate and solvent to be made into a suspension for injection. The vaccine can be given to one-day-old chicks as a single injection under the skin in the neck or directly into 18-19-day-old chicken eggs containing embryos (unhatched developing chicks).

Protection starts at 5 weeks of age for Newcastle disease, 4 weeks of age for ILT and 9 days post vaccination for Marek's disease. Protection lasts for 62 weeks after vaccination for Newcastle disease and infectious laryngotracheitis and covers the entire risk period for Marek's disease.

The medicine can only be obtained with a prescription.

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



For more information about using Innovax-ND-ILT, see the package leaflet or contact your veterinarian or pharmacist.

How does Innovax-ND-ILT work?

Innovax-ND-ILT is a vaccine. Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against a disease. The vaccine contains a type of herpesvirus which does not cause disease in chickens but which is similar to the virus that causes MD. The virus in the vaccine has been modified so that it also makes proteins from ND and ILT viruses. When Innovax-ND-ILT is given to chickens, the animals' immune system recognises the virus as 'foreign' and makes antibodies against its 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 ND, ILT and herpesvirus infections like MD.

What benefits of Innovax-ND-ILT have been shown in studies?

For MD, five laboratory studies were performed to evaluate the start of protection and the minimum requirement of 9 days could be shown for both routes of application using very virulent or virulent MDV challenges. Reduction of mortality, clinical signs and lesions caused by MD virus were demonstrated.

Eight studies were performed to determine start of protection for ND. The claim of 5 weeks is considered supported by the data presented, to reduce mortality and clinical signs of disease.

One study was performed to determine the start of protection for ILT. Vaccination of embryonated eggs or day-old birds resulted in adequate protection from clinical signs, lesions and mortality when challenged at 4 weeks of age.

No studies were performed to determine duration of immunity against MD since HVT causes a persistent infection, which is considered to provide protection for the entire risk period. Duration of immunity against ND was demonstrated at 62 weeks post vaccination, with 100% of birds protected from challenge with NDV Texas GB strain. With 93% protection from clinical signs, duration of immunity against ILTV was demonstrated at 62 weeks of age.

Efficacy was demonstrated in the field in one safety/efficacy semi-field trial for MD and one field trial for ILT.

What are the risks associated with Innovax-ND-ILT?

No side effects were observed after vaccination with Innovax-ND-ILT.

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 Innovax-ND-ILT, 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 Innovax-ND-ILT is 'zero' days, which means there is no mandatory waiting time.

Why is Innovax-ND-ILT authorised in the EU?

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

Other information about Innovax-ND-ILT

Innovax-ND-ILT received a marketing authorisation valid throughout the EU on 16 September 2020.

Further information on Innovax-ND-ILT can be found on the Agency's website:

www.ema.europa.eu/medicines/veterinary/EPAR/innovax-nd-ilt.

This overview was last updated in 12-2020.