

EMA/111761/2020 EMEA/V/C/005077

Vectormune FP ILT + AE (fowlpox, avian infectious laryngotracheitis vaccine (live, recombinant) and avian encephalomyelitis vaccine (live))

An overview of Vectormune FP ILT + AE and why it is authorised in the EU

What is Vectormune FP ILT + AE and what is it used for?

Vectormune FP ILT + AE is a veterinary vaccine used in chickens to reduce skin damage due to fowlpox (FP), to reduce the clinical signs and tracheal (windpipe) damage due to avian infectious laryngotracheitis (ILT) and to prevent loss of egg production due to avian encephalomyelitis (AE).

Vectormune FP ILT + AE contains the active substances live fowlpox virus which has been modified to produce certain proteins found in avian infectious laryngotracheitis virus and a specific strain of avian encephalomyelitis virus.

How is Vectormune FP ILT + AE used?

The medicine can only be obtained with a prescription.

Vectormune FP ILT + AE is given once from 8 to 13 weeks of age. It is given by inserting the twopronged applicator (supplied with the vaccine) from beneath through the wing web, taking care not to damage blood vessels.

For FP and ILT, protection begins 3 weeks after vaccination and for AE after 20 weeks. After vaccination, protection is expected to last 34 weeks against FP, and 57 weeks against ILT and AE.

For more information about using Vectormune FP ILT + AE, see the package leaflet or contact your veterinarian or pharmacist.

How does Vectormune FP ILT + AE work?

Vaccines work by preparing the immune system (the body's natural defences) to defend the body against specific diseases. Vectormune FP ILT + AE contains a live fowlpox virus that has been modified to produce small amounts of proteins of avian infectious laryngotracheitis virus. It also contains the Calnek 1143 strain of avian encephalomyelitis virus. Neither of the viruses in the vaccine is expected to cause disease.



 ${\ensuremath{\mathbb C}}$ European Medicines Agency, 2020. Reproduction is authorised provided the source is acknowledged.

When an animal is given the vaccine, its immune system recognises the viruses and proteins in the vaccine as 'foreign' and makes antibodies against them. In future if the animal comes into contact with the viruses and virus proteins, these antibodies, together with other components of the immune system, will be able to quickly kill the infecting viruses. This will help protect the chickens against FP, ILT and AE.

What benefits of Vectormune FP ILT + AE have been shown in studies?

No outbreaks of FP, ILT or AE occurred during 3 field studies. In all groups vaccinated with Vectormune FP ILT + AE, development of a small nodule or scab at the injection site confirmed take of the vaccine in 92–100% of animals. For the AE component, antibody levels in the blood were similar for animals vaccinated with Vectormune FP ILT + AE and those vaccinated with a comparator vaccine.

In one study, field-vaccinated animals were exposed to fowlpox virus and infectious laryngotracheitis virus at 23 or 28 weeks of age. The study indicated that use of Vectormune FP ILT + AE under field conditions reduced clinical signs of FP and reduced clinical signs and tracheal damage due to ILT virus.

Although the studies showed that antibodies against avian encephalomyelitis virus developed with Vectormune FP ILT + AE, since no field challenge occurred, no data were obtained on efficacy against this virus in field conditions.

A number of other studies contributed to information on when protection starts and how long it lasts.

What are the risks associated with Vectormune FP ILT + AE?

The most common side effects with Vectormune FP ILT + AE (which may affect more than 1 in 10 animals) are small swelling or scabs typical of fowlpox vaccine take, which usually disappear within 14 days after vaccination.

For the full list of restrictions of Vectormune FP ILT + AE, see the package leaflet.

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

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. 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 Vectormune FP ILT + AE is 'zero' days, which means that there is no mandatory waiting time.

Why is Vectormune FP ILT + AE authorised in the EU?

The European Medicines Agency decided that Vectormune FP ILT + AE's benefits are greater than its risks and it can be authorised for use in the EU.

Other information about Vectormune FP ILT + AE

Vectormune FP ILT + AE received a marketing authorisation valid throughout the EU on 24/04/2020.

Further information on Vectormune FP ILT + AE can be found on the Agency's website: ema.europa.eu/medicines/veterinary/EPAR/Vectormune FP ILT + AE.

This overview was last updated in February 2020.