



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Gumbohatch (*infectious bursal disease vaccine live attenuated*)

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

What is Gumbohatch and what is it used for?

Gumbohatch is a vaccine used to protect broiler chickens (reared for meat) against infectious bursal disease (IBD) virus infection caused by a very virulent IBD virus. Virulent means that the virus is capable of producing severe disease.

IBD, also known as Gumboro disease, is a highly contagious (spreads easily) 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 Gumboro disease include trembling, ruffled feathers, poor appetite, dehydration, diarrhoea, huddling and depression. The vaccine reduces signs of the disease and damage to the bursa of Fabricius, an organ only present in birds which is part of their immune system.

Gumbohatch contains a live strain of IBD virus (strain 1052) that has been weakened so that it does not cause the disease.

How is Gumbohatch used?

Gumbohatch is available as a freeze dried powder (lyophilisate) 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 or directly into 18-day-old chicken eggs containing embryos (unhatched developing chicks). The vaccine should be used only in flocks that are known to have maternal antibodies (transmitted from the mother) against IBD virus. Protection against IBD starts from between 24 to 28 days of age and lasts up to 43 days of age.

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

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Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us

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How does Gumbohatch work?

Gumbohatch is a vaccine. Vaccines work by preparing the immune system (the body's natural defences) to defend itself against a specific disease. Gumbohatch contains small amounts of weakened IBD virus attached to antibodies. When a chick or chicken egg is given the vaccine, the immune system recognises the weakened virus in the vaccine as 'foreign' and makes its own antibodies against the virus. When the chicken comes into contact with a similar IBD virus, these antibodies, together with other components of the chicken's immune system, will be able to fight the infection and help protect it against the disease.

What benefits of Gumbohatch have been shown in studies?

Gumbohatch was investigated in 5 laboratory and 3 field studies.

The laboratory studies involved chicks with maternal antibodies against IBD virus. The studies showed Gumbohatch to reduce clinical signs and damage to the bursa of Fabricius caused by very virulent (powerful) IBD virus infection, following vaccination of eggs or chicks.

The start of protection depends on the initial maternal antibody level of the batch of chickens and even then will be different for individual chickens. Studies have shown the start of protection to be from between 24 days of age and 28 days of age.

What are the risks associated with Gumbohatch?

Gumbohatch must not be used in flocks without maternal antibodies against IBD virus.

The most common side effect with Gumbohatch (which may affect more than 1 in 10 animals) is a fall in the number of lymphocytes (a type of white blood cell which is part of the chicken's immune system) in the bursa of Fabricius, followed by an increase and recovery of the bursa of Fabricius. This loss of lymphocytes does not cause immunosuppression in the chickens.

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?

Hands and equipment should be washed and disinfected after use of the vaccine.

After handling vaccinated birds or their litter, hands should be washed and disinfected because the virus is excreted by vaccinated birds for up to 3 weeks.

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

Why is Gumbohatch authorised in the EU?

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

Other information about Gumbohatch

Gumbohatch received a marketing authorisation valid throughout the EU on 12 November 2019.

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

This overview was last updated in September 2019.