



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Nobilis IB Primo QX (*live avian infectious bronchitis virus strain D388*)

An overview of Nobilis IB Primo QX and why it is authorised in the EU

What is Nobilis IB Primo QX and what is it used for?

Nobilis IB Primo QX is a veterinary vaccine used to protect chickens against viral infectious bronchitis caused by strains of infectious bronchitis virus known as QX-like variants, such as strain D388.

Nobilis IB Primo QX contains live attenuated (weakened) avian infectious bronchitis virus strain D388 as the active substance.

How is Nobilis IB Primo QX used?

Nobilis IB Primo QX is available as a lyophilisate (freeze-dried powder) which may be supplied with a solvent. The vaccine is to be made up into a suspension to be given to chickens from 1 day of age or older by spraying onto the chickens or by applying drops into the eyes or nostrils. The period of protection is 8 weeks.

How does Nobilis IB Primo QX work?

Nobilis IB Primo QX is a vaccine. Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against a disease. The avian infectious bronchitis virus in Nobilis IB Primo QX has been attenuated (weakened) so that it does not cause disease. When Nobilis IB Primo QX is given to chickens, the animals' immune system recognises the virus as 'foreign' and makes antibodies against it. In the future if the animals are exposed to the virus the immune system will be able to respond more quickly. This will help protect them against infectious bronchitis.

What benefits of Nobilis IB Primo QX have been shown in studies?

The effectiveness of the vaccine was first studied in a number of laboratory studies in chickens. The purpose of the studies was to establish how long it took for chickens to be fully protected, the length of time protection lasts against infectious bronchitis due to QX-like variants, as well as the influence of maternal antibodies (transmitted from the mother) on the effectiveness of the vaccine.

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The effectiveness of Nobilis IB Primo QX was investigated in two field studies.

In the first study broiler chickens (chickens bred for meat) were spray-vaccinated with both Nobilis IB Primo QX and Nobilis IB Ma5, a vaccine against a Massachusetts strain of infectious bronchitis virus. Two groups of 28 birds were challenged with the virus 3 weeks after vaccination, one group with a QX strain and the second group with another strain called M41. Control groups of birds were unvaccinated to show the effectiveness of the challenge.

In a second study 42 broiler chickens were spray vaccinated at 1 day old and challenged 3 weeks after vaccination with a QX strain of the virus. Unvaccinated chicks were retained as controls to show the effectiveness of the challenge.

The laboratory studies showed that the vaccine had its full effect by three weeks and that protection lasted for eight weeks; protection was not affected by antibodies transmitted from the mother.

In the first field study 100% of the birds vaccinated with Nobilis IB Primo QX mixed with Nobilis IB Ma5 were protected from the QX strain and 90% were protected from M41, compared with none of the unvaccinated birds.

The second field study showed 93% of the Nobilis IB Primo QX vaccinated birds and none of the unvaccinated birds to be protected from the challenge.

What are the risks associated with Nobilis IB Primo QX?

After vaccination, a mild short-lived reaction in the airways, including a nasal discharge, may occur for at least 10 days. These reactions are very rare (affecting less than 1 bird in 10,000).

For the full list of side effects and restrictions of Nobilis IB Primo QX, see the package leaflet.

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

If vaccinating by spray masks with eye protection should be worn when handling the product. Hands and equipment should be washed and disinfected after vaccination to avoid spread of the virus.

What is the withdrawal period in food-producing animals?

The withdrawal period is the time allowed after administration of the medicine and before the animal can be slaughtered and the meat used for human consumption, or eggs used for human consumption. The withdrawal period for chickens vaccinated with Nobilis IB Primo QX is zero days.

Why is Nobilis IB Primo QX authorised in the EU?

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

Other information about Nobilis IB Primo QX

Nobilis IB Primo QX received a marketing authorisation valid throughout the EU on 4 September 2014.

Further information on Nobilis IB Primo QX can be found on the Agency's website:
ema.europa.eu/medicines/veterinary/EPAR/nobilis-ib-primo-qx

This overview was last updated in 11-2020.