



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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## **EPAR summary for the public**

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# **Nobilis IB 4-91**

## **Avian infectious bronchitis vaccine (live attenuated)**

This document is a summary of the European Public Assessment Report. Its purpose is to explain how the assessment done by the Committee for Medicinal Products for Veterinary Use (CVMP) on the basis of the documentation provided, led to the recommendations on the conditions of use.

This document cannot replace a face-to-face discussion with your veterinarian. If you need more information about your animal's medical condition or treatment, contact your veterinarian. If you want more information on the basis of the CVMP recommendations, read the scientific discussion (also part of the EPAR).

### **What is Nobilis IB 4-91?**

Nobilis IB 4-91 is a veterinary vaccine that contains live attenuated (weakened) avian infectious bronchitis virus. Nobilis IB 4-91 is available as a lyophilisate (freeze-dried powder) which is to be made up into a suspension.

### **What is Nobilis IB 4-91 used for?**

Nobilis IB 4-91 is used to immunise chickens to reduce the respiratory signs of infectious bronchitis caused by the variant strain IB 4-91, which causes infectious bronchitis in chickens.

Nobilis IB 4-91 can be given to 1-day-old chicks and older chickens by coarse spray or by intranasal (breathed in through the nose) or ocular (absorbed by the eyes) administration. The vaccine can be given to 7-day and older chickens in their drinking water.

The vaccine can be administered to future layers and breeders from day old onwards via intranasal/ocular route or coarse spray. The vaccine can be administered to 7-day and older chickens by drinking water. For prolonged immunity, chickens should be revaccinated every 6 weeks after the initial administration.



## **How does Nobilis IB 4-91 work?**

Nobilis IB 4-91 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 4-91 has been attenuated (weakened) so that it does not cause disease. When Nobilis IB 4-91 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.

## **How has Nobilis IB 4-91 been studied?**

The Nobilis IB 4-91 vaccine has been studied in various vaccination schedules in a number of trials. The vaccine was given by coarse spray to chicken of various ages. The main measures of effectiveness included the development of antibodies to the IB 4-91 virus, the overall death rate of the chickens and the percentage of chicken rejected because of disease. Nobilis IB 4-91 vaccine has also been compared with controls, i.e. chickens that were not vaccinated.

## **What benefit has Nobilis IB 4-91 shown during the studies?**

There was a clear immune response to Nobilis IB 4-91. In one trial, after three weeks 100% of chickens had developed antibodies to the IB 4-91 virus compared with 17% for the controls.

## **What is the risk associated with Nobilis IB 4-91?**

Nobilis IB 4-91 can cause mild respiratory signs of disease which may last for a few days depending on the health and condition of the chickens.

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

There are no precautions for the person, but it is recommended to wash and disinfect hands and equipment after vaccinating to avoid spread of the virus.

The vaccine virus may spread from vaccinated to non-vaccinated chickens, so care should be taken to separate vaccinated from non-vaccinated chickens.

## **What is the withdrawal period?**

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

The withdrawal period for Nobilis IB 4-91 for chickens is zero days.

## **Why has Nobilis IB 4-91 been approved?**

The Committee for Medicinal Products for Veterinary Use (CVMP) agreed that the benefits of Nobilis IB 4-91 exceed the risks for the approved indication and recommended that Nobilis IB 4-91 should be given a marketing authorisation. The benefit-risk balance may be found in the scientific discussion module of this EPAR.

### **Other information about Nobilis IB 4-91:**

The European Commission granted a marketing authorisation valid throughout the European Union for Nobilis IB 4-91 on 9 June 1998. Information on the prescription status of this product may be found on the label/outer package.

This summary was last updated in March 2015.