



## EUROPEAN PUBLIC ASSESSMENT REPORT (EPAR)

### NOBILIS OR INAC

#### EPAR summary for the public

*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 OR Inac?

Nobilis OR Inac is a vaccine that contains a suspension of the bacterium *Ornithobacterium rhinotracheale* serotype A, strain B3263/91. The bacterium has been inactivated (treated to make it unable to cause an illness). Nobilis OR Inac is an emulsion (a mixture of oil- and water-based liquids) for injection.

#### What is Nobilis OR Inac used for?

Nobilis OR Inac is used to vaccinate female chickens that are being used for breeding broilers (chickens bred for meat) against the bacterium *O. rhinotracheale* serotype A. This immunity is then passed on to the chickens' offspring, so that the broilers are protected against infection with the same type of bacteria. Infection with *O. rhinotracheale* can cause respiratory diseases and death.

Nobilis OR Inac is given as two 0.25-ml injections, either under the skin in the neck or into the breast muscle. The first injection is given at an age of six to 12 weeks and the second at least six weeks later at an age of 14 to 18 weeks. Immunity is transferred to the chicken's offspring for a period of 43 weeks after the last vaccination. In the broiler chicks, the immunity lasts until at least 14 days after hatching.

#### How does Nobilis OR Inac work?

Nobilis OR Inac is a vaccine. Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against diseases. Nobilis OR Inac contains small amounts of a killed bacterium called *O. rhinotracheale* serotype A, strain B3263/91. The vaccine also contains an 'adjuvant' (liquid paraffin) to stimulate a better response. When a breeder is given the vaccine, the immune system recognises the killed bacteria as 'foreign' and makes antibodies against them. These antibodies are then passed on to the breeder's offspring through the eggs. The antibodies then protect the offspring against infection with this type of bacterium.

### **How has Nobilis OR Inac been studied?**

The effectiveness of Nobilis OR Inac has been studied in two main studies that compared the effectiveness of Nobilis OR Inac with that of no vaccination. The studies looked at the levels of antibodies against *O. rhinotracheale* in the vaccinated breeders at four weeks after the second injection of the vaccine (22 weeks of age), and again at the end of the laying period (58 weeks of age). The studies also looked at the offspring (broilers).

### **What benefit has Nobilis OR Inac shown during the studies?**

In the study, the levels of antibodies were higher in the vaccinated breeders than in those that did not receive the vaccine, both at 22 and at 58 weeks of age. The chicks of vaccinated breeders had lower death rates and produced more meat than those whose mothers had not been vaccinated.

### **What is the risk associated with Nobilis OR Inac?**

Nobilis OR Inac can cause temporary swelling at the site of injection, as well as other sporadic reactions near the injection site and affecting the whole body.  
Nobilis OR Inac should not be used in birds that are in lay (currently producing eggs).

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

Accidental injection of Nobilis OR Inac can cause severe pain and swelling, particularly if it is accidentally injected into a joint or finger. If accidental injection happens, seek prompt medical advice and show the Package Leaflet to the doctor. If pain persists for more than 12 hours after examination, seek medical advice again.

### **What is the time to allow before the animal can be slaughtered and the meat used for human consumption (withdrawal period)?**

The withdrawal period is zero days.

### **Why has Nobilis OR Inac been approved?**

The Committee for Medicinal Products for Veterinary Use (CVMP) concluded that the benefits of Nobilis OR Inac exceed the risks for passive immunisation of broilers induced by active immunisation of female broiler breeders to reduce infection with *O. rhinotracheale* serotype A when this agent is involved, and recommended that Nobilis OR Inac be given a marketing authorisation. The benefit-risk balance may be found in module 6 of this EPAR.

### **Other information about Nobilis OR Inac:**

The European Commission granted a marketing authorisation valid throughout the European Union for Nobilis OR Inac to Intervet International on 24 January 2003. Information on the prescription status of this product may be found on the label/outer package.

**This summary was last updated on 10.01.2008.**