European Medicines Agency
Veterinary Medicines

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EUROPEAN PUBLIC ASSESSMENT REPORT (EPAR)

NOBILIS INFLUENZA H7N1

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. If you need more information about how this product may be used, you should consult your national veterinary authority. If you want more information on the basis of the CVMP recommendations, read the Scientific Discussion (also part of the EPAR).

What is Nobilis Influenza H7N1?

Nobilis Influenza H7N1 is a vaccine containing an inactivated avian influenza virus H7N1 (inactivated means that the virus has been killed so that it can no longer cause the disease).

What is Nobilis Influenza H7N1 used for?

Nobilis Influenza H7N1 is a vaccine used in chickens and ducks to protect against avian influenza. The vaccine reduces the signs of flu in chickens and the excretion (shedding) and transmission (spreading) of the virus by the infected chickens and ducks. The vaccine is injected intramuscularly (into a muscle) or subcutaneously (under the skin).

The vaccine will only be used as part of an approved national disease control programme. This is because control of avian influenza is the responsibility of national veterinary authorities in consultation with the European Commission.

How does Nobilis Influenza H7N1 work?

Nobilis Influenza H7N1 is a vaccine. When it is given to chickens and ducks, the birds' immune system (their natural defence mechanism) makes antibodies (a special type of protein) to fight the disease. In the future, if the birds are exposed to the avian flu virus, the immune system will be able to make those antibodies quicker and this will help them fight the disease.
The virus used for the vaccine carries the H7 (haemagglutinin 7) and N1 (neuramidase 1) antigens. This means that vaccinated birds make antibodies against these two antigens. This strain has been chosen because it protects birds against virulent H7 field strains (cross-protection), while allowing differentiation of vaccinated from infected birds. Vaccinated birds can be differentiated identified from infected birds by a diagnostic test for antibodies against the N1 component. This differentiation is important for disease surveillance and control.

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How has Nobilis Influenza H7N1 been studied?

The company carried out laboratory studies using Nobilis Influenza H7N1 in chickens and ducks. The company also performed a laboratory study in chickens with a vaccine similar to Nobilis Influenza H7N1. This vaccine has some of the same ingredients but a different antigen (virus) to Nobilis Influenza H7N1.

The vaccine was assessed in the context of an emergency situation which means that further studies with Nobilis H7N1 are still ongoing and will be assessed.

What benefit has Nobilis Influenza H7N1 shown during the studies?

- The results of the safety studies indicated that the product is safe for chickens and ducks. When compared, the subcutaneous and intramuscular routes were shown to produce the same responses.
- The vaccine has been shown to reduce clinical signs and mortality and reduce virus shedding in infected chickens.
- The vaccine has been shown reduce virus shedding in infected ducks.
- The vaccine is able to induce antibodies in a wide range of birds.
- If the circulating avian influenza field virus has a different N component to the N1 included in the vaccine, it may be possible to differentiate between vaccinated from infected birds by using a diagnostic test to detect Neuraminidase antibodies.

What is the risk associated with Nobilis Influenza H7N1?

In common with many adjuvanted vaccines swelling may occur at the vaccination site which may last for about 14 days.

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

The vaccine contains a mineral oil. The person who injects the vaccine should be careful to avoid accidental self injection.

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

Zero days
The vaccine does not contain any ingredients that are likely to pose a risk for consumers of vaccinated birds.

Why has Nobilis Influenza H7N1 been approved?

The Committee for Medicinal Products for Veterinary use concluded that the vaccine has been shown to be effective in reducing clinical disease in poultry and could be a useful tool in controlling an outbreak of avian influenza infection. Due to the current epidemiological situation of avian influenza and the consequent threat to both human and animal health, the Committee recommended the granting of a Marketing Authorisation. The benefit-risk balance may be found in module 6 of this EPAR.

Nobilis Influenza H7N1 has been authorised under “Exceptional Circumstances”. This means that it has yet not been possible to obtain complete information about the product. The European Medicines Agency (EMEA) will review additional information that will become available according to an agreed timetable and this summary will be updated as necessary.

Other information about Nobilis Influenza H7N1:

The European Commission granted a marketing authorisation valid throughout the European Union, for Nobilis Influenza H7N1 to Intervet International BV on 14/05/2007.

This summary was last updated in May 2007.