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EPAR summary for the public

POULVAC FLUFEND H5N3 RG

Inactivated recombinant avian influenza virus

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 Poulvac FluFend H5N3 RG?

Poulvac FluFend H5N3 RG is a vaccine containing an inactivated avian influenza virus H5N3 (inactivated means that the virus has been killed so that it cannot cause the disease anymore).

What is Poulvac FluFend H5N3 RG used for?

Poulvac FluFend H5N3 RG is a vaccine used in chickens and ducks to protect against avian influenza. The vaccine reduces the signs of flu and the excretion (shedding) of the virus by the infected birds. The vaccine is injected intramuscularly (into the breast muscle) in chickens or subcutaneously (under the skin) in ducks, as two doses, 3 weeks apart.

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.

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How does Poulvac FluFend H5N3 RG work?

Poulvac FluFend H5N3 RG is a vaccine. When it is given to birds, the animals' immune systems (their natural defences) learn how to make antibodies (a special type of protein) to fight the virus. In the future, if the birds are exposed to the avian flu virus, their immune systems will be able to make those antibodies quicker and this will help them fight the disease.

The virus used for the vaccine is a recombinant virus. It has been made using a 'recombinant DNA technique' (when genes are inserted into an organism) to carry the H5 (haemagglutinin 5) and N3 (neuraminidase 3) antigens. This kind of 'reassortment' between H and N types happens naturally in the wild but in this case has been carried out in the laboratory to produce a virus with these very specific properties. Birds vaccinated with this vaccine make antibodies against these two chosen antigens. This strain has been chosen because it protects birds against the virulent H5N1 field strains (cross-protection), while allowing differentiation of vaccinated from infected birds. Vaccinated birds can be differentiated from infected birds by looking for antibodies against the N3 component. This differentiation is important for disease surveillance and control.

How has Poulvac FluFend H5N3 RG been studied?

- In chickens:

Laboratory studies were carried out looking at the safety of the vaccine after a single dose, an overdose and a repeated dose regimen. The results of studies of a similar vaccine on chickens free of any infection (containing the same ingredients, except for the virus) were also looked at. A field trial was also carried out.

- In ducks:

Laboratory studies were carried out looking at the safety of the vaccine after a single dose, an overdose and a repeated dose regimen. No field trial is available for this target species. This is acceptable because of the current political and epidemiological situation in Europe with regard to avian influenza.

The vaccine was assessed in the context of an emergency situation which means that further studies with Poulvac FluFend H5N3 RG are still ongoing and will be assessed.

What benefit has Poulvac FluFend H5N3 RG shown during the studies?

- The studies showed that the birds which receive the vaccine develop antibodies against the H5 subtype of the avian influenza virus.
- The vaccine has been shown to prevent clinical signs and mortality and reduce virus shedding in infected chickens and ducks.
- If the circulating avian influenza field virus has a different N component to the N3 included in the vaccine, it may be possible to differentiate between vaccinated and infected birds by using a diagnostic test to detect specific Neuraminidase antibodies.

What is the risk associated with Poulvac FluFend H5N3 RG?

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 gives 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 Poulvac FluFend H5N3 RG been approved?

The Committee for Medicinal Products for Veterinary Use concluded that the vaccine has been shown to be safe and to be effective in preventing disease in poultry and could be a useful tool in controlling an outbreak of avian influenza infection. Because of 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.

Poulvac FluFend H5N3 RG has been authorised under "Exceptional Circumstances". This means that it has yet not been possible to obtain complete information about Poulvac FluFend H5N3 RG. The European Medicines Agency (EMA) will review additional information that will become available according to an agreed timetable and this summary will be updated as necessary.

Other information about Poulvac FluFend H5N3 RG:

The European Commission granted a marketing authorisation valid throughout the European Union, for Poulvac FluFend H5N3 RG on 01.09.2006.

This summary was last updated on 26/10/2011.