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EPAR summary for the public

Poulvac E. coli

avian colibacillosis vaccine (live)

This is a summary of the European Public Assessment Report (EPAR) for Poulvac E. coli. It explains how the Agency assessed this veterinary medicine to recommend its authorisation in the European Union (EU) and its conditions of use.

For practical information about using Poulvac E. coli animal owners or keepers should read the package leaflet or contact their veterinarian or pharmacist.

What is Poulvac E. coli and what is it used for?

Poulvac E. coli is a vaccine that is used in chickens and turkeys for active immunisation against an infection caused by *Escherichia coli* serotype O78 called colibacillosis. Colibacillosis can cause injuries to the sac that surrounds the heart (pericarditis), the sac surrounding the liver (perihepatitis) and the 'air sacs', the specialised bags within the bird's body where air is stored during breathing (airsacculitis), and can lead to death of the bird. The vaccine, which is for use in broiler chickens (reared for meat), future layers or breeders (reared for egg production) and turkeys, helps reduce injuries and deaths caused by the infection.

It contains the live bacteria *Escherichia coli*, type O78, strain EC34195 with a gene (aroA) deleted.

How is Poulvac E. coli used?

Poulvac E. coli is available as a freeze dried powder (lyophilisate) which can be made into a suspension. It can only be obtained with a prescription. In chickens it is given as a single dose either by coarse spray vaccination from one day of age or by adding to drinking water from five days of age. In turkeys it is given by coarse spray vaccination from one day of age with a second dose three weeks later.

When giving by coarse spray vaccination the reconstituted vaccine should be diluted and sprayed onto the birds so that each bird receives enough for one dose. The birds consume the vaccine when preening their feathers.

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When adding Poulvac E. coli to drinking water a sufficient amount to supply one dose of reconstituted vaccine for every chicken should be added to as much water as is consumed by the chickens in three hours.

For further information, see the package leaflet.

How does Poulvac E. coli work?

Poulvac E. coli contains small amounts of the bacterium *E. coli* serotype O78. The bacterium is alive, but it has been weakened by removal of a gene (aroA) so that it does not cause disease, which makes it suitable for use in a vaccine. Poulvac E. coli, like all vaccines, works by 'teaching' the immune system (the body's natural defences) how to defend itself against a disease. When Poulvac E. coli is given to a chicken or turkey, the animal's immune system recognises the parts of the bacterium contained in the vaccine as 'foreign' and makes antibodies against it. In the future, if the animals are exposed to the bacteria, the immune system will be able to make antibodies more quickly. This will help protect against the disease.

What benefits of Poulvac E. coli have been shown in the studies?

Laboratory studies showed that the vaccine is safe and that protection against colibacillosis lesions starts two weeks after vaccination in chickens and three weeks after vaccination in turkeys. The studies also demonstrated that the vaccine provides chickens with eight weeks protection against colibacillosis lesions and 12 weeks protection against mortality from colibacillosis with spray vaccination and 12 weeks protection against lesions and mortality with drinking water vaccination. The field study with over 200,000 commercial broilers showed a significant reduction in colibacillosis lesions and deaths in vaccinated animals. In addition, a positive effect of the vaccine was shown on average daily weight gain, number of antibiotic treatment days and percentage of animals marketed compared to controls.

What are the risks associated with Poulvac E. coli?

The vaccine strain can be detected in tissues (liver and heart) for up to six days after vaccination in chickens or in tissues (air sacs) for up to four days after vaccination in turkeys. It may also be present in faeces for up to five weeks post vaccination in chickens or seven days post vaccination in turkeys, and remain present in the environment until the end of the finishing (time to slaughter) or rearing period for chickens or for seven days for turkeys. Therefore, it is recommended to clean and disinfect bird houses where the vaccine was administered after completion of the finishing or rearing period. The vaccine may spread to in-contact birds.

Animals undergoing antibacterial or immunosuppressive treatment (treatment that reduces the activity of the immune system) should not be vaccinated. The vaccine should not be used within six weeks before the start of the laying period or in birds in lay (currently producing eggs). Antibiotic treatment should not be given within one week before or after vaccination.

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

The use of eye-protection, gloves and a nose-mouth mask by the operator is recommended during administration. Immunosuppressed people should not be present during administration of the vaccine. Hands and equipment should be disinfected after use. Personnel involved in attending vaccinated animals should follow general hygiene principles and take particular care in handling litter from vaccinated animals.

What is the withdrawal period in food-producing animals?

The withdrawal period is the time required after administration of a medicine before an animal can be slaughtered and the meat used for human consumption. It is also the time required after administration of a medicine before eggs may be used for human consumption.

The withdrawal period for meat and eggs from chickens and turkeys treated with Poulvac E. coli is 'zero' days, which means that there is no mandatory waiting time.

Why is Poulvac E. coli approved?

The Agency's Committee for Medicinal Products for Veterinary Use (CVMP) concluded that Poulvac E. coli's benefits are greated that its risks and recommended that it be approved in the EU.

Other information about Poulvac E. coli:

The European Commission granted a marketing authorisation valid throughout the European Union, for Poulvac E. coli on 15 June 2012. Information on the prescription status of this product can be found on the label/outer package.

The full EPAR for Poulvac E. coli can be found on the Agency's website: ema.europa.eu/Find medicine/Veterinary medicines/European public assessment reports. For more information about treatment with Poulvac E. coli, animal owners or keepers should read the package leaflet or contact their veterinarian or pharmacist.

This summary was last updated in February 2016.