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## **EPAR** summary for the public

## **Evalon**

avian coccidiosis vaccine (live)

This is a summary of the European public assessment report (EPAR) for Evalon. It explains how the Agency assessed this veterinary medicine to recommend its authorisation in the European Union (EU) and its conditions of use. It is not intended to provide practical advice on how to use Evalon.

For practical information about using Evalon, animal owners or keepers should read the package leaflet or contact their veterinarian or pharmacist.

#### What is Evalon and what is it used for?

Evalon is a veterinary vaccine to protect chickens against coccidiosis caused by the coccidia parasites *Eimeria acervulina*, *Eimeria brunetti*, *Eimeria maxima*, *Eimeria necatrix* and *Eimeria tenella*. Coccidiosis is a disease of the gut which results in reduced growth, severe diarrhoea, reduced egg production and a high death rate. Infected birds shed disease spores (oocysts) in their faeces that can spread the infection.

The vaccine contains live attenuated (weakened) oocysts of *Eimeria acervulina*, *Eimeria brunetti*, *Eimeria maxima*, *Eimeria necatrix* and *Eimeria tenella*.

## How is Evalon used?

Evalon is available as a suspension and solvent and can only be obtained with a prescription. The vaccine is given to one-day-old chicks by coarse spray vaccination. The vaccine suspension should be diluted with the solvent and water according to dosing instructions and sprayed onto the birds so that each bird receives one dose. The birds consume the vaccine when preening their feathers. Protection starts at 3 weeks after vaccination and lasts until 60 weeks after vaccination.

For further information, see the package leaflet.



### How does Evalon work?

Evalon is a vaccine. Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against a disease. The vaccine contains the oocysts of *Eimeria* species that have been weakened so that they cannot cause disease. When Evalon is given to chickens, the animals' immune system recognises the *Eimeria* oocysts as foreign and makes defences against them. In the future if the animals are exposed to the same *Eimeria* species the immune system will be able to respond more quickly. This will help protect against coccidiosis.

The vaccine solvent contains the adjuvant montanide IMS to enhance the immune response.

#### What benefits of Evalon have been shown in studies?

In a field study involving 4 farms, shedding of oocysts in the faeces was reduced within 3 weeks of vaccination both in Evalon vaccinated chicks and those vaccinated with another vaccine against *Eimeria*. The results with Evalon and the comparator vaccine were similar for 3 out 4 farms; on 1 farm Evalon vaccinated chickens showed better protection than those given the comparator.

#### What are the risks associated with Evalon?

There are no known side effects with Evalon. For the full list of restrictions, see the package leaflet.

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

Safety information has been included in the summary of product characteristics and the package leaflet for Evalon, including the appropriate precautions to be followed by healthcare professionals and animal owners or keepers.

Hands and equipment should be washed and disinfected after use.

#### 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 treated with Evalon is 'zero' days, which means there is no mandatory waiting time.

## Why is Evalon approved?

The Agency's Committee for Medicinal Products for Veterinary Use (CVMP) concluded that Evalon's benefits are greater than its risks and recommended that it be approved for use in the EU.

## Other information about Evalon?

The European Commission granted a marketing authorisation valid throughout the EU for Evalon on 18/04/2016.

The full EPAR for Evalon 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 Evalon, animal owners or keepers should read the package leaflet or contact their veterinarian or pharmacist.

This summary was last updated in February 2016.