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EPAR summary for the public

Coliprotec F4

E. coli O8:K87 vaccine (live)

This 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 Coliprotec F4?

Coliprotec F4 is a vaccine that is available as a lyophilisate (a freeze-dried pellet) which is made up into an oral suspension with water. It contains live *Escherichia coli* (*E.coli*) bacteria of a strain (O8:K87) that does not produce toxins that cause disease.

What is Coliprotec F4 used for?

Coliprotec F4 is given to pigs from 18 days of age to reduce the incidence of moderate to severe post-weaning *E. coli* diarrhoea. Although *E.coli* is naturally found in the gut, some strains (known as enterotoxigenic strains) produce a toxin that causes diarrhoea, and can result in dehydration, weight loss and occasionally death of the animal.

Coliprotec F4 is given orally to pigs as a single dose either as a drench or by addition to the drinking water. The vaccine starts to be effective 7 days after vaccination and protection lasts for 21 days after vaccination.

How does Coliprotec F4 work?

Coliprotec F4 is a vaccine. Vaccines work by 'teaching' the immune system (the body's natural

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defences) how to defend itself against a disease. The types of *E.coli* associated with post-weaning diarrhoea often produce a protein called F4 on their outer coat that allows them to attach to the cells of the gut. The strain of bacteria in the vaccine have this protein but do not produce the toxin that causes the disease. When Coliprotec F4 is given to pigs, the animals' immune system recognises the bacteria as 'foreign' and makes antibodies against them. In the future, if the animals are exposed to disease-causing bacteria with the F4 protein, the immune system will be able to respond more quickly. This will help protect the pigs against *E. coli* infection and disease.

How has Coliprotec F4 been studied?

The effectiveness of the vaccine was first studied in a number of laboratory studies in pigs. The purpose of these studies was to establish how long it took for pigs to be fully protected and the length of time protection lasts against *E. coli*.

The effectiveness of Coliprotec F4 was investigated in two field studies involving pigs where the farms had a history of post-weaning diarrhoea. In each study 350 pigs were vaccinated with Coliprotec F4 and 350 pigs remained unvaccinated. The main measure of effectiveness was the number of pigs developing diarrhoea.

What benefit has Coliprotec F4 shown during the studies?

Both field studies showed that vaccination with Coliprotec F4 reduced the number of pigs with moderate to severe diarrhoea.

What is the risk associated with Coliprotec F4?

Shivering may be seen in more than 1 in 10 pigs after vaccination.

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

Personal protective equipment consisting of protective disposable gloves and safety glasses should be worn when handling the vaccine.

In case of accidental ingestion and/or spillage onto skin, medical advice should be sought immediately and the package leaflet or the label shown to the doctor.

What is the withdrawal period?

The withdrawal period is the time allowed after administration of the medicine and before the animal can be slaughtered and the meat used for human consumption.

The withdrawal period for Coliprotec F4 for pigs is zero days.

Why has Coliprotec F4 been approved?

The CVMP concluded that the benefits of Coliprotec F4 exceed the risks for the approved indication and recommended that Coliprotec F4 be given a marketing authorisation. The benefit-risk balance may be found in the scientific discussion module of this EPAR.

Other information about Coliprotec F4:

The European Commission granted a marketing authorisation valid throughout the European Union, for Coliprotec F4 on 16 March 2015. Information on the prescription status of this product may be found on the label/outer package.

This summary was last updated in January 2015.