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## EPAR summary for the public

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# Coliprotec F4/F18

*E. coli* O8:K87 / O141:K94 vaccine (live)

This is a summary of the European public assessment report (EPAR) for Coliprotec F4/F18. 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 Coliprotec F4/F18.

For practical information about using Coliprotec F4/F18, animal owners or keepers should read the package leaflet or contact their veterinarian or pharmacist.

## What is Coliprotec F4/F18 and what is it used for?

Coliprotec F4/F18 is a vaccine used to protect pigs from 18 days of age against post-weaning diarrhoea caused by *E. coli*. Although *E. coli* bacteria are naturally found in the gut, some strains (known as enterotoxigenic strains) produce toxins that cause diarrhoea and can result in dehydration, weight loss and occasionally death of the animal. This is more likely to occur at weaning time when the piglet no longer receives protecting antibodies through the sow's milk.

Coliprotec F4/F18 contains two strains of live *E. coli* bacteria (O8:K87 and O141:K94) which do not produce toxins that cause disease.

## How is Coliprotec F4/F18 used?

Coliprotec F4/F18 is available as a lyophilisate (a freeze-dried pellet) which is made up into a suspension with water to be given by mouth.

Coliprotec F4/F18 is given by mouth 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. The medicine can only be obtained with a prescription.

For further information, see the package leaflet.



## **How does Coliprotec F4/F18 work?**

Coliprotec F4/F18 is a vaccine. Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against a disease. The types of *E. coli* associated with post-weaning diarrhoea often produce proteins called F4 and F18 on their outer coat that allows them to attach to the cells of the gut. The strains of bacteria in the vaccine have these proteins but do not produce the toxins that cause the disease.

When Coliprotec F4/F18 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 or F18 proteins, the immune system will be able to respond more quickly. This will help protect the pigs against the infection and reduce the risk of disease.

## **What benefits of Coliprotec F4/F18 have been shown in studies?**

The effectiveness of the vaccine was studied in four laboratory studies in pigs that looked chiefly at the incidence, severity and duration of diarrhoea as well as the presence of disease-causing *E. coli* in the animals' excrement. Pigs aged 17 – 18 days were vaccinated with Coliprotec F4/F18 and then artificially infected with *E. coli* strains. Two studies used the F4 strain while the other two used the F18 strain. The vaccine reduced the number of pigs with moderate to severe diarrhoea compared to non-vaccinated pigs. Two studies showed the vaccine starts to be effective 7 days after vaccination and two studies showed protection lasts for 21 days after vaccination.

## **What are the risks associated with Coliprotec F4/F18?**

There are currently no known side effects associated with Coliprotec F4/F18.

## **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, medical advice should be sought immediately and the package leaflet or label shown to the doctor. In case of spillage onto skin, the affected area should be rinsed with water and medical advice should be sought immediately and the package leaflet or label shown to the doctor.

## **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.

The withdrawal period for meat from pigs treated with Coliprotec F4/F18 is 'zero' days, which means there is no mandatory waiting time.

## **Why is Coliprotec F4/F18 approved?**

The Agency's Committee for Medicinal Products for Veterinary Use (CVMP) concluded that Coliprotec F4/F18's benefits are greater than its risks and recommended that it be approved for use in the EU.

## **Other information about Coliprotec F4/F18?**

The European Commission granted a marketing authorisation valid throughout the EU for Coliprotec F4/F18 on 9 January 2017.

The full EPAR for Coliprotec F4/F18 can be found on the Agency's website: [ema.europa.eu/Find/medicine/Veterinary medicines/European public assessment reports](http://ema.europa.eu/Find/medicine/Veterinary%20medicines/European%20public%20assessment%20reports). For more information about treatment with Coliprotec F4/F18, animal owners or keepers should read the package leaflet or contact their veterinarian or pharmacist.

This summary was last updated in November 2016.