



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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## EPAR summary for the public

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# Porcilis ColiClos

## E. Coli and C. perfringens vaccine

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 Porcilis ColiClos?

Porcilis ColiClos is a vaccine that is available as a suspension for injection. It contains parts of the *Escherichia coli* (*E. coli*) bacterium called fimbrial adhesins F4ab, F4ac, F5 and F6 and LT toxoid (weakened toxin), as well as toxoid of the *Clostridium perfringens* (*C. perfringens*) bacterium type C.

### What is Porcilis ColiClos used for?

Porcilis ColiClos is given to sows (female pigs that have already given birth to piglets) or gilts (female pigs that have not yet given birth to piglets) to provide their offspring with protection against infections caused by *E. coli* strains that express the components F4ab, F4ac, F5 or F6, and by *C. perfringens* type C. The vaccine is used to reduce death and clinical signs of infections caused by these bacteria during the first days of life.

Porcilis ColiClos is given by injection into a muscle in the neck area behind the ear. The first injection is given to sows or gilts, six or eight weeks before the expected farrowing (giving birth) date and a second injection is given four weeks later. Sows that have been vaccinated according to this scheme before need a single revaccination two to four weeks before the expected farrowing date.



## **How does Porcilis ColiClos work?**

Porcilis ColiClos is a vaccine. Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against a disease. Porcilis ColiClos contains parts of the bacteria *E. coli* and *C. perfringens* that have been inactivated so that they cannot cause disease. When Porcilis ColiClos is given to sows or gilts, the pig's immune system recognises the inactivated bacteria as 'foreign' and makes antibodies against them. These antibodies are transferred from the mother to the piglets through the colostrum (first milk), and they help the piglets to fight *E. coli* or *C. perfringens* infection if they become exposed after birth.

Porcilis ColiClos contains an adjuvant to enhance the immune response.

## **How has Porcilis ColiClos been studied?**

The company has presented data from both laboratory and field studies on the effectiveness of the vaccine against the two bacteria. To demonstrate protection against *E. coli* infection, studies were also presented with Porcilis Porcoli Diluvac Forte, a vaccine authorised within the EU with the same *E. coli* components as Porcilis ColiClos.

## **What benefit has Porcilis ColiClos shown during the studies?**

Porcilis ColiClos has been shown to reduce death and the clinical signs of *E. coli* or *C. perfringens* infections such as neonatal piglet diarrhoea and necrotic enterotoxaemia (a severe infection of the intestines). It may also reduce the use of antimicrobials in pig production units.

## **What is the risk associated with Porcilis ColiClos?**

An increase in body temperature of up to 2°C may be observed on the day of vaccination. Reduced activity and lack of appetite on the day of vaccination commonly occurs. A sometimes painful and hard swelling up to 10 cm in diameter may be observed at the injection site for up to 25 days.

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

In case of accidental self-injection, medical advice should be sought immediately and the package leaflet or the label shown to the physician.

## **What is the withdrawal period?**

The withdrawal period is the time allowed after administration of the medicine before the animal can be slaughtered and the meat used for human consumption or eggs or milk used for human consumption. The withdrawal period for Porcilis ColiClos is zero days for pig meat.

## **Why has Porcilis ColiClos been approved?**

The Committee for Medicinal Products for Veterinary Use (CVMP) concluded that the benefits of Porcilis ColiClos exceed the risks and recommended that Porcilis ColiClos be given a marketing authorisation. The benefit/risk balance can be found in the scientific discussion module of this EPAR.

### **Other information about Porcilis ColiClos:**

The European Commission granted a marketing authorisation valid throughout the European Union, for Porcilis ColiClos on 14 June 2012. Information on the prescription status of this product can be found on the label/outer package.

This summary was last updated on 14 June 2012.