



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Enteroporc Coli (*neonatal piglet colibacillosis vaccine (recombinant, inactivated)*)

An overview of Enteroporc Coli and why it is authorised in the EU

What is Enteroporc Coli and what is it used for?

Enteroporc Coli is a veterinary vaccine 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 protect their offspring from intestinal disease caused by *Escherichia coli* (*E. coli*). It contains parts of the *E. coli* bacterium called fimbrial adhesins F4ab, F4ac, F5 and F6.

How is Enteroporc Coli used?

Enteroporc Coli can only be obtained with a prescription and is available as an injection. It is given into the neck muscles behind the ear of pregnant female pigs. The initial vaccination course is two injections given 3 weeks apart, with the second injection given 2 weeks before the expected date of farrowing (giving birth). In each subsequent pregnancy, sows that have previously been vaccinated according to this schedule should be given a single revaccination two weeks before the expected farrowing date.

For more information about using Enteroporc Coli, see the package leaflet or contact your veterinarian or pharmacist.

How does Enteroporc Coli work?

Enteroporc Coli is a vaccine. Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against a disease. Enteroporc Coli contains inactivated parts of the bacterium *E. coli* that cannot cause disease. When Enteroporc Coli is given to sows or gilts, the pig's immune system recognises the inactivated bacterial parts as 'foreign' and makes antibodies against them. These antibodies are transferred from the mother to the piglets through the colostrum (first milk) and help the piglets to fight *E. coli* infection if they become exposed after birth. Protection of the progeny starts within 12 hours after birth and lasts for the first days of life.

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Enteroporc Coli also contains aluminium hydroxide which acts as an adjuvant (an ingredient that strengthens the immune response).

What benefits of Enteroporc Coli have been shown in studies?

Enteroporc Coli has been shown to reduce death and/or the clinical signs of *E. coli* infection such as neonatal piglet diarrhoea.

Four laboratory studies conducted in newborn piglets showed that protection against *E. coli* infection began within 12 hours, which is expected to last for the first days of life. In addition, one laboratory study conducted in sows confirmed efficacy after revaccination, as determined by antibody titres in colostrum.

Data from three field studies were presented in support of the results of the laboratory studies, where efficacy was determined by protective levels of antibody titres in colostrum of vaccinated gilts.

What are the risks associated with Enteroporc Coli?

The most common side effects with Enteroporc Coli (which may affect more than 1 in 10 animals) are an increase in body temperature that can occur on the day of vaccination and may last up to 24 hours and swelling or redness at the injection site that resolves without treatment within 7 days. Slightly depressed behaviour (which may affect up to 1 in 10 animals) can be observed on the day of vaccination.

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

None.

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 Enteroporc Coli is 'zero' days, which means that there is no mandatory waiting time.

Why is Enteroporc Coli authorised in the EU?

The European Medicines Agency decided that Enteroporc Coli's benefits are greater than its risks and it can be authorised for use in the EU.

Other information about Enteroporc Coli

Enteroporc Coli received a marketing authorisation valid throughout the EU on 6 January 2021.

Further information on Enteroporc Coli can be found on the Agency's website: ema.europa.eu/medicines/veterinary/EPAR/enteroporc-coli.

This overview was last updated in 02-2021.