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Suiseng Diff/A (*Clostridioides difficile and Clostridium perfringens vaccine, inactivated)*

An overview of Suiseng Diff/A and why it is authorised in the EU

What is Suiseng Diff/A and what is it used for?

Suiseng Diff/A 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 toxins produced by the bacteria *Clostridioides difficile* (toxins A and B) and *Clostridium perfringens* type A (alpha toxin). Suiseng Diff/A contains versions of the toxins that have been inactivated so they cannot cause disease, called toxoid A, toxoid B and alpha toxoid.

How is Suiseng Diff/A used?

Suiseng Diff/A can only be obtained with a prescription and is available as a suspension for injection. It is given into the neck muscles of pregnant pigs. The initial vaccination course is two injections given three weeks apart, with the second injection given three weeks before farrowing (giving birth). In each following pregnancy, sows that have previously been vaccinated according to this schedule should be given a single revaccination three weeks before the expected farrowing date.

How does Suiseng Diff/A work?

Suiseng Diff/A is a vaccine. Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against a disease. Suiseng Diff/A contains inactivated toxins produced by the bacteria *Clostridioides difficile* and *Clostridium perfringens* type A. When Suiseng Diff/A is given to sows or gilts, the pig's immune system recognises the inactivated bacterial toxins 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 *Clostridioides difficile* or *Clostridium perfringens* type A infections if they become exposed to the bacteria after birth. Protection of the offspring starts within 24 hours after birth and lasts up to 28 days of life in the majority of piglets.

Suiseng Diff/A also contains adjuvants (aluminium hydroxide, ginseng extract and diethylaminoethyl-dextran) to stimulate a better immune response.

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What benefits of Suiseng Diff/A have been shown in studies?

Suiseng Diff/A has been shown to prevent death and reduce the clinical signs, such as neonatal piglet diarrhoea, and intestinal lesions caused by *Clostridioides difficile* toxins A and B, and to reduce the clinical signs and intestinal lesions caused by *Clostridium perfringens* alpha toxin.

Two laboratory studies were conducted in newborn piglets to assess the efficacy of Suiseng Diff/A. The first study showed that protection began 24 hours after birth. The second study confirmed the effectiveness after revaccination.

Data from one field study were presented to support the results of the laboratory studies, where a reduction in the occurrence of neonatal piglet diarrhoea was demonstrated. This study also demonstrated that protective antibodies lasted for up to 28 days in the majority of piglets.

What are the risks associated with Suiseng Diff/A?

The most common side effects with Suiseng Diff/A (which may affect up to 1 in 10 animals) are a transient increase in body temperature on the day of vaccination and swelling at the injection site that resolves without treatment within five days.

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 vaccinated with Suiseng Diff/A is 'zero' days, which means that there is no mandatory waiting time.

Why is Suiseng Diff/A authorised in the EU?

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

Other information about Suiseng Diff/A

Suiseng Diff/A received a marketing authorisation valid throughout the EU on 07/12/2021.

Further information on Suiseng Diff/A can be found on the Agency's website: ema.europa.eu/medicines/veterinary/EPAR/suiseng-diff.

This overview was last updated in 11-2021.