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Aftovaxpur DOE (*Foot-and-mouth disease vaccine, killed*)

An overview of Aftovaxpur DOE and why it is authorised in the EU

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What is Aftovaxpur DOE and what is it used for?

Aftovaxpur DOE is a vaccine used to vaccinate cattle, sheep and pigs from two weeks of age against foot-and-mouth disease. Foot-and-mouth disease affects cloven-hoofed animals and causes fever, followed by blisters on the inside of the mouth and on the feet, which may rupture and lead to lameness. Aftovaxpur DOE contains up to three strains of inactivated (killed) foot-and-mouth disease virus. These strains belong to four different serotypes (types) of the virus known as O, A, Asia 1 and SAT2, and are selected, depending on the epidemiological need, from the following eight strains: O1 Manisa, O1 BFS, O Taiwan 3/97, A22 Iraq, A24 Cruzeiro, A Turkey 14/98, Asia 1 Shamir and SAT2 Saudi Arabia.

How is Aftovaxpur DOE used?

Aftovaxpur DOE is available as a liquid emulsion for injection and can only be obtained with a prescription. The vaccine is given to cattle and sheep as an injection under the skin whilst for pigs the injection is given into a muscle. Revaccination is required every six months. When animals are vaccinated at 2 weeks of age, revaccination is recommended at 8 to 10 weeks.

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

How does Aftovaxpur DOE work?

Aftovaxpur DOE is a vaccine. Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against a disease. Aftovaxpur DOE contains strains of foot-and-mouth disease virus that have been inactivated so they cannot cause the disease. When it is given to cattle, pigs and sheep, the immune system recognises the virus as 'foreign' and makes antibodies against it. In the future, if the animals are exposed to foot-and-mouth disease virus, the immune system will be able to produce antibodies more quickly. This will help protect them against the disease.

Aftovaxpur DOE contains an adjuvant (liquid paraffin) to enhance the immune response.

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What benefits of Aftovaxpur DOE have been shown in studies?

Laboratory studies for the individual strains were conducted in cattle or pigs. One, two or four weeks after vaccination animals were exposed to the appropriate strain of live foot-and-mouth disease virus. The measure of effectiveness was the reduction in clinical signs of foot-and-mouth disease. Some studies also looked at the levels of antibodies in cattle, sheep and pigs after single and repeated doses of the vaccine. In addition, studies in published papers were provided, which examined the effect of vaccination in cattle, sheep, and pigs.

No field studies were conducted. This was considered acceptable, given the laboratory data and taking into account that vaccination against foot–and-mouth disease is currently not permitted in the EU under legal controls on foot-and-mouth disease.

The studies showed that Aftovaxpur DOE leads to adequate blood levels of antibodies against foot-and-mouth disease strains following a single vaccination. Vaccine containing O1 Manisa antigen reduces clinical signs of foot-and-mouth disease in cattle, sheep and pigs. Sufficient justification for extrapolation of these data to other strains was provided. The start of protection is 1 week after vaccination in cattle and sheep and 4 weeks after vaccination in pigs.

The range of antibodies produced following vaccination with Aftovaxpur DOE was different from that produced by natural infection; this makes it possible to distinguish vaccinated from infected animals, which is important for disease control.

What are the risks associated with Aftovaxpur DOE?

Swellings (up to 12 cm diameter in ruminants and 4 cm in pigs) at the injection site occur in most animals after vaccination. They usually resolve over a four-week period after vaccination but may last longer in a small number of animals.

A slight increase in rectal temperature, of up to 1.2 °C for 4 days, may affect up to 1 in 10 animals following vaccination.

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

Aftovaxpur DOE is an emulsion containing liquid paraffin. Accidental injection of liquid paraffin may cause severe pain and swelling, particularly if injected into a joint or finger – this could result in the loss of the finger if prompt medical attention is not given. If someone is accidentally injected with this product, they must seek medical advice immediately even if only a very small amount is injected. The package leaflet should be shown to the doctor. If pain persists for more than 12 hours after medical examination, the doctor should be contacted again.

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. It is also the time required after administration of a medicine before milk may be used for human consumption. The withdrawal period for meat and milk from cattle and sheep and for meat from pigs treated with Aftovaxpur DOE is ‘zero’ days which means that there is no mandatory waiting time.

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Why is Aftovaxpur DOE authorised in the EU?

The European Medicines Agency decided that Aftovaxpur DOE's benefits are greater than its risks and it be approved for use in the EU.

Other information about Aftovaxpur DOE

Aftovaxpur DOE received a marketing authorisation valid throughout the EU on 15 July 2013.

Further information can be found on the Agency's website: ema.europa.eu/medicines/veterinary/EPAR/aftovaxpur-doe.

This summary was last updated in November 2018.

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