European Medicines Agency
Veterinary Medicines

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EUROPEAN PUBLIC ASSESSMENT REPORT (EPAR)

PORCILIS PESTI

EPAR summary for the public

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 Pesti?

Porcilis Pesti is an emulsion for injection. Porcilis Pesti contains Classical Swine Fever Virus -E2 subunit antigen.

What is Porcilis Pesti used for?

Porcilis Pesti is used to immunise healthy pigs from the age of 5 weeks onwards to prevent death and to reduce clinical signs of Classical Swine Fever (CSF). It is also used to reduce infection with CSF and excretion of CSF virus into the environment.

The vaccine is shaken before use and an intramuscular (into a muscle) injection of one dose (2 ml) is given in the neck behind the ear. This first dose is followed by a second injection 4 weeks later. The pigs should be re-vaccinated every 6 months. Protection from CSF starts after 2 weeks and lasts for 6 months.

How does Porcilis Pesti work?

Porcilis Pesti contains an antigen – E2 (a substance that stimulates an immune response) to CSF. When this antigen is injected, this small exposure helps the pig's immune system to recognise and attack CSF. When exposed to CSF later in life, the pig will either not become infected or have a much less serious infection.

How has Porcilis Pesti been studied?

Porcilis Pesti has been studied in two safety field trials, one in finishing pigs and one in sows using different vaccination doses. The field trials confirm the results obtained in the laboratory safety experiments and show that the product is safe for the target animal (piglets from 5 weeks of age onwards) and in the most sensitive category of animals (pregnant sows).

The main measure of effectiveness in a field trial with piglets was the survival of the piglets when exposed to the CSF virus later in life. The piglets were also tested for viraemia (presence of virus in their blood). The start and length of immunity was measured by antibodies produced by the piglets to the CSF antigen (E2). Maternally derived antibodies did not interfere with vaccination.

7 Westferry Circus, Canary Wharf, London E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 84 16
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

What benefit has Porcilis Pesti shown during the studies?

All the vaccinations prevented death when the piglets were exposed to CSF virus at a later date. Viraemia was only prevented by two injections (as recommended in the vaccination schedule for Porcilis Pesti). Antibodies to the CSF antigen showed that the piglets developed immunity after 2 weeks, which was maintained for 6 months.

What is the risk associated with Porcilis Pesti?

Porcilis Pesti can cause a swelling at the injection site for up to 4 weeks after each injection of the vaccine. Temporary hyperthermia (increased temperature) may occur after the second injection. Abscesses may be seen at the injection site. It is recommended that the second vaccination is given at a different site than the first vaccination.

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

Porcilis Pesti contains mineral oil. Accidental injection may cause severe pain and swelling, particularly if injected into a joint or finger – rarely causing the loss of a finger. If someone is accidentally injected with this product, they must seek immediate medical advice even if only a very small amount is injected. The package leaflet should be taken to the doctor. If pain persists for more than 12 hours after medical examination, the doctor should be contacted again.

Why has Porcilis Pesti been approved?

The Committee for Medicinal Products for Veterinary Use (CVMP) agreed that the benefits of Porcilis Pesti are greater than any risks to immunise pigs from the age of 5 weeks onwards to prevent death and to reduce clinical signs of Classical Swine Fever. They recommended that Porcilis Pesti should be given a marketing authorisation. The benefit-risk balance may be found in module 6 of this EPAR.

Other information about Porcilis Pesti:

The European Commission granted a marketing authorisation valid throughout the European Union for Porcilis Pesti to Intervet International B.V. on 9 February 2000, which was renewed in February 2005.

The import, sale, supply and/or use of Porcilis Pesti is only allowed under the particular conditions established by European Community legislation on the control of CSF (Council Directive 80/217/EEC, as amended). Any person intending to import, sell, supply and/or use the veterinary medicinal product must be authorised by the competent authority of the Member State.

This summary was last updated in December 2006.