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EPAR summary for the public

Porcilis AR-T DF

Vaccine to reduce atrophic rhinitis in piglets

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 AR-T DF?

Porcilis AR-T DF is a vaccine for use in (female) pigs to reduce atrophic rhinitis in their piglets. Porcilis AR-T DF is a suspension for injection which contains a non-toxic recombinant derivative (see 'How does Porcilis AR-T DF work?') of the *Pasteurella multocida* toxin and inactivated *Bordetella bronchiseptica* cells.

What is Porcilis AR-T DF used for?

Porcilis AR-T DF is used to reduce the clinical signs of progressive atrophic rhinitis (a disease where the nose tissues become infected and die) in piglets. The vaccine is given to sows (female pigs) only. Their piglets then become immunised when they drink the colostrum (first milk).

Porcilis AR-T DF is given as a dose of 2 ml by intramuscular (into a muscle) injection to female pigs of 18 weeks of age and older. The vaccine is given just behind the ear. The first injection should be given 6 weeks before the expected date of farrowing (giving birth to the piglets). The first dose is followed by a second injection 4 weeks later. To maintain the immunity, a single injection of one dose should be carried out 2 – 4 weeks before each subsequent farrowing.

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How does Porcilis AR-T DF work?

Progressive atrophic rhinitis is caused by toxins from the bacteria *Pasteurella multocida*. Porcilis AR-T DF contains a non-toxic recombinant derivative (see later) of the *Pasteurella multocida* toxin and also inactivated *Bordetella bronchiseptica* bacterial cells. This bacterium is often present with *Pasteurella multocida* and makes the disease worse. When the sow is injected, this small exposure helps the pig's immune system to recognise and attack the bacteria. When exposed to any of these bacteria later in life, the pig will either not become infected or have a much less serious infection. This immunity is passed onto the sow's piglets through her colostrum.

An active ingredient of Porcilis AR-T DF, *Pasteurella multocida* toxin, is produced by a method known as 'recombinant technology'. The *Pasteurella multocida* toxin is made by a bacterium cell that has received a gene (DNA), which makes it able to produce *Pasteurella multocida* toxoid, a genetically modified form of toxin which has adequate immunogenic activity and which is free from the toxic properties.

How has Porcilis AR-T DF been studied?

Porcilis AR-T DF has been studied in sows, where it was compared with another vaccine for progressive atrophic rhinitis. In this study, blood was taken from piglets in each litter born from each sow, and tested for antibodies to *Pasteurella multocida* toxin and *Bordetella bronchiseptica*.

The length of time that Porcilis AR-T DF is effective has also been studied. The main measure of effectiveness was the amount of antibodies to *Bordetella bronchiseptica* and also to *Pasteurella multocida* toxin.

What benefit has Porcilis AR-T DF shown during the studies?

The trials showed good protection against the clinical signs of progressive atrophic rhinitis. The piglets had comparable levels of antibodies against progressive atrophic rhinitis as obtained with another approved vaccine.

In the study of the duration of effect, based on antibody levels, it was shown that revaccination with a single dose resulted in a clear booster response (that is, the resultant antibody levels were even higher than after the basic vaccination).

The vaccine was generally well tolerated and shown to be safe.

What is the risk associated with Porcilis AR-T DF?

Porcilis AR-T DF can cause a temporary increase in body temperature of 1.5°C, and in some pigs of up to 3°C on the day of vaccination or the following day. Other side effects are reduced activity and lack of appetite in 10-20% of the pigs on the day of vaccination and/or a temporary swelling (maximum diameter: 10 cm) for up to two weeks at the injection site.

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

If someone is accidentally injected with this product, they should seek immediate medical advice immediately. The Package Leaflet should be taken to the doctor.

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. The withdrawal period for Porcilis AR-T DF for pigs is zero days.

Why has Porcilis AR-T DF been approved?

The Committee for Medicinal Products for Veterinary Use (CVMP) agreed that the benefits of Porcilis AR-T DF exceed the risks for the reduction of clinical signs of progressive atrophic rhinitis in piglets, by passive oral immunisation with colostrum from dams actively immunised with the vaccine, and recommended that Porcilis AR-T DF should be given a marketing authorisation. The benefit/risk balance may be found in the scientific discussion module of this EPAR.

Other information about Porcilis AR-T DF:

The European Commission granted a marketing authorisation valid throughout the European Union for Porcilis AR-T DF to Intervet International B.V. on 16 November 2000. Information on the prescription status of this product may be found on the outer package.

This summary was last updated in September 2011.