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EPAR summary for the public

RHINISENG

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Inactivated vaccine to prevent progressive and non-progressive atrophic rhinitis in pigs

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 RHINISENG?

Rhiniseng is a vaccine containing a non-toxic recombinant derivative of the *Pasteurella multocida* toxin and inactivated *Bordetella bronchiseptica* cells (inactivated means that the bacteria are killed so that they cannot cause the disease anymore). Rhiniseng is presented in fluid form as a suspension for injection which is stored in a glass or plastic bottle.

What is RHINISENG used for?

RHINISENG is used for the protection of piglets via the sow's colostrum (first milk) after injection of sows and gilts. It is used to reduce the clinical signs and lesions of a disease called progressive and non-progressive atrophic rhinitis, as well as to reduce weight loss associated with *Bordetella bronchiseptica* and *Pasteurella multocida* infections during the fattening period.

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How does RHINISENG work?

RHINISENG is a vaccine against a bacterial disease. When it is given to sows, the animal's immune system (their natural defence mechanism) learns how to make antibodies (a special type of protein) to fight the disease. These antibodies are then transferred to the piglets via the colostrum they receive. In the future, if the sows are exposed to the above mentioned bacteria, the immune system will be able to make those antibodies quicker and this will help their piglets to fight the disease and its after effects such as weight loss.

How has RHINISENG been studied?

The safety of RHINISENG was demonstrated in several well conducted and reported laboratory and field studies. Results demonstrated that the vaccination of sows, gilts and boars according to the vaccination programme did not provoke unacceptable local or systemic reactions after vaccination and no significant differences in reproductive parameters between vaccinated and placebo-treated animals were recorded either.

Overall, the safety of this vaccine has been well documented and reported for the target animals, the user, the consumer and the environment.

The efficacy of RHINISENG was demonstrated for the category of the target species for which the vaccine is recommended (gilts and sows) by the recommended route of administration (intramuscular) using the proposed schedule of administration (first vaccination at 6-8 weeks before farrowing and revaccination 3-4 weeks later). The field efficacy results supported those obtained from the laboratory studies.

What benefit has RHINISENG shown during the studies?

Direct therapeutic benefit

RHINISENG reduces the incidence and severity of the disease called progressive and non-progressive atrophic rhinitis in pigs.

Additional benefits

As a consequence of reduced atrophic rhinitis disease, the incidence of respiratory symptoms and subsequent treatment with antibiotics of the pigs is also reduced. The pigs, which have received antibodies against progressive atrophic rhinitis via colostrum, need a shorter time to reach the slaughter weight.

What is the risk associated with RHINISENG?

The risk using this inactivated vaccine can be classified as minimal.

Main potential risks for the vaccine as such:

- for the target animal: there are mild and transitory local reactions at the injection site, resolving within few days and a transiently elevated body temperature within acceptable limits. This is reflected in the relevant sections of the SPC.
- for the user: accidental self-injection is the only identified risk and an appropriate warning has been included in the SPC to reflect the (small) risk.
- for the environment: no risk identified from the use of this inactivated vaccine

- for the consumer: all components have been investigated and no risk for the consumer has been identified.

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

In case of accidental self-injection only a minor injection site reaction is expected.

What is the time to allow before the animal can be slaughtered and the meat used for human consumption (withdrawal period)?

Zero days.

Why has RHINISENG been approved?

The Committee for Medicinal Products for Veterinary Use (CVMP) concluded that the benefits of RHINISENG exceed the risks for the treatment of piglets via colostrum from sows and gilts actively immunised with the vaccine to prevent the clinical signs and lesions of progressive and non-progressive atrophic rhinitis and recommended that RHINISENG be given a marketing authorisation. The benefit-risk balance may be found in the scientific discussion module of this EPAR.

Other information about RHINISENG:

The European Commission granted a marketing authorisation valid throughout the European Union, for RHINISENG to Laboratorios Hipra S.A. on 16/09/2010. Information on the prescription status of this product may be found on the label/outer package.

This summary was last updated on 16/09/2010.