15 July 2010
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Veterinary Medicine and Product Data Management

Committee for Medicinal Products for Veterinary Use

Summary of opinion*

RHINISENG

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

On 14 July 2010 the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion,** recommending the granting of a marketing authorisation for the veterinary medicinal product RHINISENG, suspension for injection.

The Applicant for this veterinary medicinal product is Laboratorios Hipra S.A..

The active substance of RHINISENG is
Inactivated *Bordetella bronchiseptica*, strain 833CER: 9.8 BbCC(*)
Recombinant Type D *Pasteurella multocida* toxin (PMTr): ≥ 1 MED63(**)
(*) *Bordetella bronchiseptica* Cell Count in log10.
(**) Murine Effective Dose 63: vaccination of mice with 0.2 ml of a 5-fold diluted vaccine by subcutaneous route induces seroconversion in at least 63% of the animals.

The main benefits of RHINISENG are the passive protection of piglets via colostrum after active immunisation of sows and gilts to reduce the clinical signs and lesions of 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. Challenge studies have demonstrated that passive immunity lasts until piglets are 6 weeks of age while in clinical field trials, the beneficial effects of vaccination (reduction in nasal lesion score and weight loss) are observed until slaughter.

The most common side effects are transient local reactions which may occur after the administration of one dose of vaccine. A transient slight swelling of less than 2 to 3 cm in diameter is common at the injection site which may last up to five days and occasionally up to two weeks.

A transient increase in body temperature of about 0.7°C is common during the first 6 hours after injection. An increase of rectal temperature up to 2ºC may occur. This rectal temperature increase is spontaneously resolved within 24 hours without treatment.

* Summaries of opinion are published without prejudice to the Commission Decision, which will normally be issued within 90 days from adoption of the Opinion.
** Applicants may appeal any CVMP opinion, provided they notify the EMA in writing of their intention to appeal within 15 days of receipt of the opinion.

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Detailed conditions for the use of this product will be described in the Summary of Product Characteristics (SPC) which will be published in the European Public Assessment Report (EPAR) and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CVMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit to risk balance for RHINISENG and therefore recommends the granting of the marketing authorisation.