10 December 2010
EMA/CVMP/144109/2010
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1]

Purevax Rabies

Rabies recombinant canarypox virus (vCP65)

On 8 December 2010, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion,[2] recommending the granting of a marketing authorisation for the veterinary medicinal product Purevax Rabies, a suspension for injection, intended for the active immunisation of cats 12 weeks of age and older to prevent mortality due to rabies infection. The applicant for this veterinary medicinal product is MERIAL.

The active substance of Purevax Rabies, an immunological medicinal product, is rabies recombinant canarypox virus (vCP65), a recombinant Canarypox virus expressing the glycoprotein G gene of rabies virus. After inoculation, the virus expresses the protective protein, but does not replicate in the cat. As a consequence, the vaccine stimulates active immunity against rabies virus in cats.

The benefits of Purevax Rabies are the active immunisation of cats 12 weeks of age and older to prevent mortality due to rabies infection.

The most common side effects are a transient and slight apathy, as well as occasionally mild anorexia or hyperthermia (above 39.5 °C), lasting usually 1 or 2 days. Most of these reactions appear during the 2 days following the vaccine injection. A transient local reaction may occasionally occur (pain at palpation, limited swelling that may become nodular, heat at the injection site, and in some cases erythema), that usually disappears within 1 or 2 weeks at most. Very rarely, a hypersensitivity reaction may occur, which may require appropriate symptomatic treatment.

The approved indication is: “Active immunisation of cats 12 weeks of age and older to prevent mortality due to rabies infection. Onset of immunity: 4 weeks after the primary vaccination course. Duration of immunity: 1 year”.

[1] Summaries of opinion are published without prejudice to the Commission Decision, which will normally be issued within 90 days from adoption of the opinion.
[2] Applicants may appeal any CVMP opinion, provided they notify the European Medicines Agency 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 Purevax Rabies and therefore recommends the granting of the marketing authorisation.