9 March 2012
EMA/CVMP/129854/2012
Committee for Medicinal Products for Veterinary Use

Post-authorisation summary of opinion*

Cerenia

International non-proprietary name (INN): Maropitant

On 8 March 2012, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion,** recommending the granting of a variation to the terms of the marketing authorisation for the veterinary medicinal product Cerenia. The marketing authorisation holder for this veterinary medicinal product is Pfizer Limited.

The change agreed by the CVMP concerns a new target species (cats) for the solution for injection. The proposed indication is the prevention of vomiting and the reduction of nausea, except that induced by motion sickness; and the treatment of vomiting, in combination with other supportive measures.

Moderate to severe response to injection is very commonly observed in approximately one third of cats.

Detailed conditions for the use of this product will be described in the updated summary of product characteristics (SPC) which will be published in the revised European public assessment report (EPAR) and will be available in all official European Union languages after the variation/extension to the marketing authorisation has been granted by the European Commission.

* Summaries of opinion are published without prejudice to the Commission Decision.
** 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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