9 November 2012
EMA/CVMP/683698/2012
Committee for Medicinal Products for Veterinary Use

Post-authorisation summary of opinion*

Onsior

Robenacoxib

On 8 November 2012, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a final opinion following a re-examination for one aspect of the opinion for a grouped variation** to the terms of the marketing authorisation for the veterinary medicinal product Onsior. The marketing authorisation holder for this veterinary medicinal product is Novartis Animal Health (UK) Ltd.

The final changes agreed by the CVMP concern new indications, i.e. the use of Onsior solution for injection for the treatment of pain and inflammation associated with orthopaedic surgery in cats and the use of Onsior tablets for cats for the reduction of moderate pain and inflammation associated with orthopaedic surgery as well as the additional warnings in the product literature following a PSUR assessment.

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 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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