11 July 2012
EMA/CVMP/203470/2012
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1]

Onsior

Robenacoxib

On 11 July 2012, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted an opinion for a grouped variation[2] 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 changes agreed by the CVMP concern a new indication for cats, i.e. the use of Onsior solution for injection in the treatment of pain and inflammation associated with orthopaedic surgery, and 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.

[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.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8447
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union