

9 November 2012 EMA/CVMP/584720/2012 Committee for Medicinal Products for Veterinary Use

Post-authorisation summary of opinion*

Procox

Emodepside and Toltrazuril

On 8 November 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 Procox oral suspension for dogs. The marketing authorisation holder for this veterinary medicinal product is Bayer Animal Health GmbH.

The change agreed by the CVMP concerns the addition of a new therapeutic indication for the treatment of *Trichuris vulpis* (mature adults) in dogs.

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.

^{**} 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.



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