16 July 2010
EMEA/CVMP/401633/2010
Veterinary Medicine and Product Data Management

Committee for Medicinal Products for Veterinary Use

Post authorisation summary of opinion*

Advocate EMEA/V/C/076/II/014

International Non-proprietary Name (INN): Imidacloprid and moxidectin

On 14 July 2010, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion,** recommending approval of a variation to the terms of the marketing authorisation for the veterinary medicinal product Advocate. The Marketing Authorisation Holder for this veterinary medicinal product is Bayer Animal Health GmbH.

The changes agreed by the CVMP concern the addition of a new indication for the treatment and prevention of lungworm in dogs, a revised indication for canine demodicosis and some minor administrative corrections.

This variation adds an indication for the treatment of *Crenosoma vulpis* lungworm infections in dogs, and the prevention of angiostrongylosis (L4 larvae and immature adults of *Angiostrongylus vasorum)* to the other existing indications for Advocate for Dogs.

Additionally the wording of part of the SPC which concerns the treatment of demodicosis (caused by *Demodex canis*) has been revised (see section 4.9), and some other minor editorial corrections and amendments made to the product's SPCs, labelling and package leaflets.

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, which will normally be issued within 90 days from adoption of the Opinion.
** Applicants may appeal any CVMP opinion, provided they notify the EMA in writing of their intention to appeal within 15 days of receipt of the opinion.

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