10 July 2015
EMA/CVMP/467847/2015
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (post-authorisation)

Advocate

International non-proprietary name (INN): imidacloprid / moxidectin

On 9 July 2015, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted an opinion[2] recommending the granting 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 therapeutic indication for Advocate spot-on solution for dogs, i.e. treatment of cutaneous dirofilariosis (adult stages of *Dirofilaria repens*) and to change the administrative information concerning local representatives.

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.
[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.

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