19 January 2018
EMA/CVMP/825952/2017
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (post-authorisation)

Advocate

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

On 18 January 2018, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive 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.

Advocate is currently authorised as spot-on solution. This grouped variation concerns the change of the current indications for Advocate spot-on solution for cats and ferrets / for dogs to add the following therapeutic indications:

- the treatment of the lungworm *Eucoleus aerophilus* (syn. *Capillaria aerophila*) in cats;

- the treatment of *Eucoleus* (syn. *Capillaria*) *boehmi* in dogs;

- the treatment of the eye worm *Thelazia callipaeda* in dogs.

Furthermore, the product information for Advocate for dogs was amended with regard to pharmacokinetics and some administrative information.

Detailed conditions for the use of this product are described in the updated summary of product characteristics (SPC), for which an updated version reflecting the changes 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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