



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

19 July 2013
EMA/CVMP/428221/2013
Committee for Medicinal Products for Veterinary Use

Summary of opinion¹ (post-authorisation)

Advocate

International non-proprietary names (INNs): imidacloprid / moxidectin

On 18 July 2013, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion² 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 change agreed by the CVMP concerns the addition of a new therapeutic indication for the treatment of notoedric mange (*Notoedres cati*) in cats, the treatment of circulating microfilariae (*Dirofilaria immitis*) in dogs, the reduction of circulating microfilariae (*Dirofilaria repens*) in dogs, the prevention of cutaneous dirofilariosis (L3 larvae of *Dirofilaria repens*) in dogs, and the prevention of spirocercosis (*Spirocerca lupi*) 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.

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.

