European Medicines Agency
Veterinary Medicines and Inspections

London, 20 April 2009
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COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE
POST-AUTHORISATION SUMMARY OF OPINION[*]
ADVOCATE

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

On 16 April 2009, 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 change agreed by the CVMP concerns the addition of a new target species, ferrets.

The indication is for ferrets suffering from, or at risk from, mixed parasitic infections - for the treatment and prevention of flea infestation (*Ctenocephalides felis*) and the prevention of heartworm disease (L3 and L4 larvae of *Dirofilaria immitis*).

The 0.4 ml pipette size of the 10% imidacloprid & 1% moxidectin strength (called "Advocate Spot-on solution for Small Cats") only should be used for ferrets. Advocate for Large Cats and Advocate for Dogs (all sizes) are therefore contra-indicated accordingly.

One treatment (the contents of one pipette applied to the skin of the animal's neck at the base of the skull) prevents future flea infestations for 3 weeks. For the prevention of heartworm disease, the product must be applied at regular monthly intervals during the time of the year when mosquitoes (the intermediate hosts which carry and transmit heartworm larvae) are present.

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 EMEA in writing of their intention to appeal within 15 days of receipt of the opinion.

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