



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

19 July 2019
EMA/CVMP/370703/2019
Committee for Medicinal Products for Veterinary Use

Summary of opinion¹ (post-authorisation)

BROADLINE

International non-proprietary name (INN): fipronil / (S)-methoprene / eprinomectin / praziquantel

On 18 July 2019, 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 BROADLINE. The marketing authorisation holder for this veterinary medicinal product is Merial.

BROADLINE is currently authorised as spot-on solution in cats with, or at risk from mixed infestations by cestodes, nematodes and ectoparasites, as listed in the approved product information. The veterinary medicinal product is exclusively indicated when all three parasite groups are targeted at the same time.

This variation was to add a new therapeutic indication: treatment of infections with *Ancylostoma ceylanicum* (L4 larvae and adults).

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.

