EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 October 2013
EMA/CVMP/575422/2013
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

Broadline

Fipronil, eprinomectin, praziquantel and (S)-methoprene

On 10 October 2013, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion[2], recommending the granting of a marketing authorisation for the veterinary medicinal product Broadline, 24.9 mg / 1.2 mg / 24.9 mg / 30 mg, spot-on solution, intended for cats with existing, or at risk from, mixed parasitic infections. The applicant for this veterinary medicinal product is MERIAL.

Broadline is an anti-parasitic medicinal product (ATC vet code: QP54AA). The active substances are eprinomectin, fipronil, (S)-methoprene and praziquantel. Eprinomectin is an endectocide, which causes an increase in the permeability of the cell membrane to chloride ions, resulting in paralysis and death of the parasite. Fipronil works on channels in the cells of the nervous system of ticks and fleas, blocking the transfer of ions in and out of cells, which results in uncontrolled activity of the central nervous system and death of these parasites. (S)-Methoprene is an insect growth regulator, effective in preventing flea larvae and pupae from developing. Praziquantel damages the skin-like outer layer of tapeworms, leading to their paralysis and death.

The benefits of Broadline are its well-conducted laboratory efficacy trials and clinical studies which showed that the product is efficacious for mixed infestations by ectoparasites, nematodes and cestodes. The most common side effects are a temporary clumping or spiking of the hair at the application site. Mild and transient skin reactions at the application site (itching, hair loss) may occur. Such signs resolve spontaneously within 24 hours.

Detailed conditions for the use of this product will be described in the summary of product characteristics (SPC) which will be published in the European public assessment report (EPAR) and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CVMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit to risk balance for Broadline and therefore recommends the granting of the marketing authorisation.

[1] Summaries of opinion are published without prejudice to the Commission Decision, which will normally be issued within 90 days from adoption of the opinion.
[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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