15 May 2017
EMA/CVMP/259214/2017
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (post-authorisation)

Broadline

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

On 12 May 2017, 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 Broadline. The marketing authorisation holder for this veterinary medicinal product is MERIAL.

Broadline is a medicinal product containing four active substances: fipronil, (S)-methoprene, eprinomectin and praziquantel. It is currently authorised as spot-on solution for the treatment of cats with, or at risk of infestations by cestodes (Dipylidium caninum, Taenia taeniaeformis, Echinococcus multilocularis), nematodes (feline lungworms - L3 larvae, L4 larvae and adults of Aelurostrongylus abstrusus) and prevention of heartworm disease (Dirofilaria immitis larvae).

The change agreed by the CVMP concerns the addition of the following new therapeutic indications in the target species:

- treatment of infestations with cestodes *Joyeuxiella pasqualei* (adults) and *Joyeuxiella fuhrmanni* (adults);
- treatment of infestation with the respiratory nematode *Troglostrongylus brevior* (L4 and adults).

The most common adverse reactions (they resolve spontaneously within 24 hours) in animals are:

- a temporary clumping or spiking of the hair at the application site after treatment;
- itching, hair loss;
- temporary excessive salivation - if the cat licks the application site after treatment;
- ataxia, disorientation, apathy and pupil dilation – after oral ingestion.

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

[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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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.