EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

19 July 2013
EMA/CVMP/374777/2013
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

Trifexis

Spinosad, milbemycin oxime

On 17 July 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 Trifexis chewable tablets for dogs, intended for the treatment and prevention of flea (*Ctenocephalides felis*) infestations in dogs when the concurrent prevention of heartworm disease (L3, L4 *Dirofilaria immitis*) and/or treatment of gastrointestinal nematode infections caused by hookworm (L4, immature adult (L5) and adult *Ancylostoma caninum*), roundworms (immature adult L5, and adult *Toxocara canis* and adult *Toxascaris leonina*) and whipworm (adult *Trichuris vulpis*) is indicated. Trifexis can be used as part of a treatment strategy for the control of flea allergy dermatitis (FAD). The applicant for this veterinary medicinal product is Eli Lilly and Company Limited.

The active substances of Trifexis are spinosad and milbemycin oxime. Spinosad is a mixture of spinosyns, a group of systemically acting insecticides. The activity of milbemycin is related to its action on invertebrate neurotransmission. The tablets are available in five different strengths containing spinosad and milbemycin oxime as follows: 270 mg/4.5 mg; 425 mg/7.1 mg; 665 mg/11.1 mg; 1040 mg/17.4 mg, and 1620 mg/27 mg.

The benefits of Trifexis are its efficacy in the treatment and prevention of flea infestations with concurrent prevention of heartworm disease and/or treatment of certain specified gastrointestinal nematode infections in dogs. Another benefit is its rapid speed of killing adult fleas on the dog, and also its preventive effect against re-infestations which lasts for up to 4 weeks after a single administration of the product. The most commonly observed adverse reaction is vomiting, which usually occurs in the first 48 hours after dosing. Although such vomiting post-treatment is relatively common, in the majority of cases the vomiting is transient, mild and does not require symptomatic treatment. Other commonly observed adverse reactions were diarrhoea, lethargy, anorexia/decreased appetite, pruritus, dermatitis, and reddening of the skin and the pinna.

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

[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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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 Trifexis and therefore recommends the granting of the marketing authorisation.