10 December 2010
EMA/CVMP/499406/2010
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1]

Comfortis

Spinosad

On 8 December 2010, 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 Comfortis 270mg / 425 mg / 665 mg / 1040 mg / 1620 mg chewable tablets for dogs. Comfortis tablets are intended for the treatment and prevention of flea infestations (*Ctenocephalides felis*) in dogs.

The applicant for this veterinary medicinal product is Eli Lilly and Company Limited.

The active substance of Comfortis is spinosad. Spinosad is a mixture of spinosyns, which are a novel group of systemically acting insecticides (ATCvet code: QP53BX03). The insecticidal activity of spinosad relies on adult fleas taking a blood meal from the treated dog. The active substance in the dog's blood then passes into the flea and causes nervous excitation leading to muscle contractions and tremors, prostration, paralysis and then rapid death of the flea. These effects are caused primarily by the activation of nicotinic acetylcholine receptors in the flea.

The benefits of Comfortis include 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 (as a result of the adulticidal activity of spinosad and the reduction in egg production). Additional benefits include its safety for other animals and people in the household who come into contact with the treated animal, its safety for the environment, and the lack of any reported resistance in fleas to spinosad to date.

The most common side effect is vomiting, which most commonly 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.

The approved indication is for the treatment and prevention of flea infestations (*Ctenocephalides felis*) in dogs. The preventive effect against re-infestations is a result of the adulticidal activity and the

[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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reduction in egg production and persists for up to 4 weeks after a single administration of the product. Comfortis can be used as part of a treatment strategy for the control of Flea Allergy Dermatitis (FAD).

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 Comfortis chewable tablets for dogs and therefore recommends the granting of the marketing authorisation.