EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

13 September 2013
EMA/CVMP/490575/2013
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (post-authorisation)

Comfortis - Extension

International non-proprietary name (INN): spinosad

On 12 September 2013, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion[2], recommending the granting of an extension to the terms of the marketing authorisation for the veterinary medicinal product Comfortis. The applicant for this veterinary medicinal product is Eli Lilly and Company Limited.

Comfortis is currently authorised as tablets for dogs (strengths of 90 mg, 140 mg, 270 mg, 425 mg, 665 mg, 1040 mg, and 1620 mg) and for cats (strengths of 90 mg, 140 mg, 270 mg and 425 mg). This extension application concerns the addition of a new tablet strength of 180 mg which can be used in dogs and cats within certain weight ranges. The route of administration is oral.

The active substance of Comfortis is spinosad, an ectoparasiticide for systemic use (ATCvet code: QP53BX03). The insecticidal activity of spinosad is characterised by nervous excitation leading to muscle contractions and tremors, prostration, paralysis and rapid death of the flea.

The benefits of Comfortis are its rapid speed of killing adult fleas, 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).

The most common side effect in dogs and cats is vomiting occurring within 48 hours after dosing. In the majority of cases the vomiting is transient, mild and does not require symptomatic treatment. Other commonly observed adverse reactions in cats were diarrhoea and anorexia.

The approved indication is for treatment and prevention of flea infestations (*Ctenocephalides felis*) in dogs and cats. The preventive effect against re-infestations is a result of the adulticidal activity and the reduction in egg production and persists for up to 4 weeks after a single administration of the product. The veterinary medicinal product 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 are described in the summary of product characteristics (SPC) which is published in the European public assessment report (EPAR) and is available in all official

[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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The CVMP, on the basis of data submitted, considers that there is a favourable benefit to risk balance for Comfortis 180 mg chewable tablets for dogs and cats and therefore recommends the granting of the extension of the marketing authorisation.