9 November 2012
EMA/CVMP/676652/2012
Committee for Medicinal Products for Veterinary Use

Post-authorisation summary of opinion*

Comfortis - Extension

Common name: spinosad

On 8 November 2012, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion, ** recommending the granting of a (grouped) extension to the terms of the marketing authorisation for the veterinary medicinal product Comfortis. The marketing authorisation holder for this veterinary medicinal product is Eli Lilly and Company Limited.

Comfortis is currently authorised as tablets for dogs (strengths of 270 mg, 425 mg, 665 mg, 1040 mg, and 1620 mg). The changes agreed by CVMP for this grouped extension (and variation) application concern the addition of cats as a new target species, and also the addition of two new lower strength tablets (90 mg and 140 mg) which can be used in small dogs as well as in cats. The tablets are to be administered to dogs and/or cats orally.

The benefits of Comfortis tablets for cats include its rapid speed of killing adult fleas on the cat, 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 adverse event in 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 indications for both dogs and cats are: Treatment and prevention of flea infestations (*Ctenocephalides felis*). 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).

* Summaries of opinion are published without prejudice to the Commission Decision.
** 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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Detailed conditions for the use of this product will be described in the updated summary of product characteristics (SPC) which will be published in the revised European public assessment report (EPAR) and will be available in all official European Union languages after the extension to the marketing authorisation has been granted by the European Commission.