



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

13 December 2013  
EMA/CVMP/700673/2013  
Committee for Medicinal Products for Veterinary Use

## Summary of opinion<sup>1</sup> (initial authorisation)

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### NexGard

International non-proprietary name (INN): Afoxolaner

On 12 December 2013, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion<sup>2</sup>, recommending the granting of a marketing authorisation for the veterinary medicinal product NexGard chewable tablets for dogs (11 mg, 28 mg, 68 mg, 136 mg). The applicant for this veterinary medicinal product is Merial.

The active substance of NexGard is afoxolaner, a new ectoparasiticide belonging to the isoxazoline group, which is systemically active against ticks and fleas. The benefits of NexGard are its efficacy in the treatment of flea and tick infestations on dogs. The product is in general well tolerated at the recommended dose, adverse reactions (gastrointestinal effects) were only observed in overdoses.

The recommended indication is:

Treatment of flea infestation in dogs (*Ctenocephalides felis* and *C. canis*) for at least 5 weeks. Can be used as part of a treatment strategy for the control of Flea Allergy Dermatitis (FAD).

Treatment of tick infestation in dogs (*Dermacentor reticulatus*, *Ixodes ricinus*, *Rhipicephalus sanguineus*). One treatment kills ticks for up to one month.

Fleas and ticks must attach to the host and commence feeding in order to be exposed to the active substance. For fleas (*C. felis*), the onset of effect is within 8 hours of attachment. For ticks, the onset of effect (death) is within 48 hours of attachment.

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 NexGard and therefore recommends the granting of the marketing authorisation.

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<sup>1</sup> Summaries of opinion are published without prejudice to the Commission Decision, which will normally be issued within 90 days from adoption of the opinion.

<sup>2</sup> 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.

