14 September 2018
EMA/CVMP/525858/2018
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (post-authorisation)

NEXGARD SPECTRA; NexGard

International non-proprietary name (INN): afoxolaner / milbemycin oxime; afoxolaner

On 13 September 2018, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion[2], recommending the granting of a variation to the terms of the marketing authorisation for the veterinary medicinal products NEXGARD SPECTRA and NexGard. The marketing authorisation holder for these veterinary medicinal products is MERIAL.

NEXGARD SPECTRA is currently authorised as chewable tablets for the treatment of flea (*Ctenocephalides felis* and *C. canis*) and tick (*Dermacentor reticulatus, Ixodes ricinus* and *Rhipicephalus sanguineus*) infestations in dogs when the concurrent prevention of heartworm disease (*Dirofilaria immitis* larvae), angiostrongylosis (reduction of the level of infection with immature adults (L5) and adults of *Angiostrongylus vasorum*) and/or treatment of gastrointestinal nematode infestations (roundworms (*Toxocara canis* and *Toxascaris leonina*), hookworms (*Ancylostoma caninum, Ancylostoma braziliense* and *Ancylostoma ceylanicum*) and whipworm (*Trichuris vulpis*)) is indicated.

NexGard is currently authorised as chewable tablets for the treatment of flea (*Ctenocephalides felis* and *C. canis*) and tick (*Dermacentor reticulatus, Ixodes ricinus* and *Rhipicephalus sanguineus*) infestations in dogs, and as part of a treatment strategy for the control of flea allergy dermatitis.

This variation was to add new therapeutic indications: for the treatment of demodicosis (caused by *Demodex canis*) and sarcoptic mange (caused by *Sarcoptes scabiei* var. *canis*).

Detailed conditions for the use of these products are described in their updated summary of product characteristics (SPC), for which an updated version reflecting the changes will be published in the revised European public assessment report (EPAR) and will be available in all official European Union languages after the variation to the marketing authorisation has been granted by the European Commission.

[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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