19 July 2019
EMA/CVMP/369028/2019
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 18 July 2019, 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 and tick infestations in dogs when the concurrent prevention of heartworm disease, angiostrongylosis and/or treatment of gastrointestinal nematode infestations is indicated. The product is also indicated for the treatment of demodicosis and sarcoptic mange.

NexGard is currently authorised as chewable tablets for the treatment of flea and tick infestations, as part of a treatment strategy for the control of flea allergy dermatitis, for the treatment of demodicosis and for the treatment of sarcoptic mange in dogs.

This variation was to add a new therapeutic indication: treatment of tick infestations with *Ixodes hexagonus*.

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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