19 July 2019
EMA/CVMP/369202/2019
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (post-authorisation)

NEXGARD SPECTRA

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

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 product NEXGARD SPECTRA. The marketing authorisation holder for this veterinary medicinal product 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.

This variation was to add a new therapeutic indication: prevention of establishment of thelaziosis (adult *Thelazia callipaeda* eyeworm infection).

Detailed conditions for the use of this product are described in the 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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