9 December 2022
EMA/CVMP/924541/2022
Committee for Veterinary Medicinal Products (CVMP)

Summary of opinion[1] (post-authorisation)

Nexgard Spectra

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

On 8 December 2022, the Committee for Veterinary Medicinal Products (CVMP) adopted a positive opinion[2], recommending the granting of a group of variations to the terms of the marketing authorisation following a worksharing procedure for the veterinary medicinal products Nexgard Spectra and NexGard. The marketing authorisation holder for these veterinary medicinal products is Boehringer Ingelheim Vetmedica GmbH.

Nexgard Spectra and NexGard are currently authorised as chewable tablets for use in dogs. The group of variations is to add two new therapeutic indications for the treatment of tick infestations with *Hyalomma marginatum* and for the treatment of ear mite infestations (caused by *Otodectes cynotis*), and to amend the product information to allow the use of the product in breeding, pregnant and lactating female dogs. In addition, the applicant takes the opportunity to make an editorial change in section 6.5 of the SPC for both products.

Detailed conditions for the use of these products are described in the 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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