13 June 2025
EMADOC-1700519818-2201538
Committee for Veterinary Medicinal Products (CVMP)

Summary of opinion[1] (post-authorisation)

NexGard

International non-proprietary name (INN): Afoxolaner

On 12 June 2025, 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 for the veterinary medicinal products NexGard and NexGard Spectra following a worksharing procedure. The marketing authorisation holder for these veterinary medicinal products is Boehringer Ingelheim Vetmedica GmbH.

NexGard and NexGard Spectra are currently authorised as chewable tablets for use in dogs. The grouped variation concerns change(s) to therapeutic indication(s): addition of a new therapeutic indication or modification of an approved one: for reduction of the risk of infection with *Babesia canis canis* via transmission by *Dermacentor reticulatus* for 28 days and for reduction of the risk of infection with *Dipylidium caninum* via transmission by *Ctenocephalides felis* for 30 days.

Detailed conditions for the use of these products are described in the summary of product characteristics (SPC), for which updated versions reflecting the changes will be published in the Union Product Database (UPD) 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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