10 September 2021
EMA/CVMP/483593/2021
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (post-authorisation)

Frontpro

International non-proprietary name (INN): afoxolaner

On 9 September 2021, 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 Frontpro. The marketing authorisation holder for this veterinary medicinal product is Boehringer Ingelheim Vetmedica GmbH.

Frontpro is currently authorised as chewable tablets for use in dogs. The variation concerns the change of legal status from prescription-only to non-prescription veterinary medicine. Additionally, the applicant is adding the list of local representatives to the package leaflet.

Detailed conditions for the use of this product 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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