8 October 2021
EMA/CVMP/523501/2021
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (post-authorisation)

Apoquel

International non-proprietary name (INN): oclacitinib maleate

On 7 October 2021, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion[2], recommending the granting of an extension to the terms of the marketing authorisation for the veterinary medicinal product Apoquel. The marketing authorisation holder for this veterinary medicinal product is Zoetis Belgium SA.

Apoquel is currently authorised as film-coated tablet. The extension concerns the addition of a new pharmaceutical form (chewable tablet).

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 extension 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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