17 February 2023
EMA/CVMP/39823/2023
Committee for Veterinary Medicinal Products (CVMP)

Summary of opinion[1] (post-authorisation)

Zeleris

International non-proprietary name (INN): florfenicol / meloxicam

On 15 February 2023, 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 product Zeleris. The marketing authorisation holder for this veterinary medicinal product is CEVA Santé Animale.

Zeleris is currently authorised as solution for injection for use in cattle. The grouped variation concerns the addition of a new therapeutic indication for the treatment of bovine respiratory disease due to *Mycoplasma bovis* associated with pyrexia and the alignment of the product information with version 9.0 of the QRD templates.

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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