11 September 2020
EMA/CVMP/446877/2020
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (post-authorisation)

Cytopoint

Common name: lokivetmab

On 9 September 2020, 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 Cytopoint. The marketing authorisation holder for this veterinary medicinal product is Zoetis Belgium SA.

Cytopoint is currently authorised as solution for injection. The variation concerns to add a new therapeutic indication for the treatment of pruritus associated with allergic dermatitis in dogs. As a consequence, section 4.2 of the SPC and section 4 of the PL are updated accordingly. The MAH also took the opportunity to add a dog pictogram in point 7 of the package leaflet.

Detailed conditions for the use of this product are described in the updated 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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