17 February 2023
EMA/CVMP/66932/2023
Committee for Veterinary Medicinal Products

Summary of opinion[1] (initial authorisation)

Prolevare

International non-proprietary name (INN): oclacitinib maleate

On 15 February 2023, the Committee for Veterinary Medicinal Products (CVMP) adopted a positive opinion[2], recommending the granting of a marketing authorisation for the veterinary medicinal product Prolevare film-coated tablets for dogs. The applicant for this veterinary medicinal product is Zoetis Belgium.

Prolevare contains oclacitinib maleate (ATCvet code QD11AH90) as active substance, a janus kinase (JAK) inhibitor, which inhibits the production of pro-inflammatory cytokines in various types of cells.

The application for Prolevare was an informed consent application. In an informed consent application, reference is made to an authorised medicine where the marketing authorisation holder of the reference medicine has given consent to the use of their dossier in the application procedure. The reference product for Prolevare is Apoquel (EU/2/13/154/001–036).

The full indication is: "Treatment of pruritus associated with allergic dermatitis in dogs" and "Treatment of clinical manifestations of atopic dermatitis in dogs".

Detailed conditions for the use of this product are described in the summary of product characteristics (SPC), which will be published in the Union Product Database (UPD) and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CVMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit-risk balance for Prolevare and therefore recommends the granting of the marketing authorisation.

[1] Summaries of opinion are published without prejudice to the Commission Decision, which will normally be issued 67 days from adoption of the opinion.
[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.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

© European Medicines Agency, 2023. Reproduction is authorised provided the source is acknowledged.