EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

19 July 2013
EMA/CVMP/322909/2013
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

APOQUEL

International non-proprietary name (INN): Oclacitinib maleate

On 18 July 2013, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion[2] recommending the granting of a marketing authorisation for the veterinary medicinal product APOQUEL film-coated tablets for dogs, intended for the treatment of pruritus associated with allergic dermatitis, and for the treatment of clinical manifestations of atopic dermatitis. The applicant for this veterinary medicinal product is Zoetis Belgium S.A.

The active substance of APOQUEL is oclacitinib (as oclacitinib maleate), a Janus kinase (JAK) inhibitor, which can inhibit the function of a variety of cytokines dependent on JAK enzyme activity. For oclacitinib, the target cytokines are those that are proinflammatory or have a role in allergic responses/pruritis. The tablets are available in three different strengths, 3.6 mg, 5.4 mg and 16 mg.

The benefits of APOQUEL are its efficacy in the treatment of pruritus associated with allergic dermatitis in dogs, and in the treatment of clinical manifestations of atopic dermatitis in dogs. The most common side effects are diarrhoea, vomiting, anorexia, new cutaneous or subcutaneous lumps, lethargy and polydipsia. APOQUEL may increase susceptibility to infection and exacerbate neoplastic conditions.

Detailed conditions for the use of this product will be described in the summary of product characteristics (SPC) which will be published in the European public assessment report (EPAR) 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 to risk balance for APOQUEL 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 within 90 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.

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