8 November 2024
EMA/CVMP/490426/2024
Committee for Veterinary Medicinal Products

Summary of opinion[1] (initial authorisation)

Carprofen Orion

International non-proprietary name (INN): Carprofen

On 7 November 2024, the Committee for Veterinary Medicinal Products (CVMP) adopted a positive opinion[2], recommending the granting of a marketing authorisation for the veterinary medicinal product Carprofen Orion, Chewable tablet; Solution for injection, intended for Cat and Dog. The applicant for this veterinary medicinal product is Orion Corporation.

The active substance of Carprofen Orion is carprofen (QM01AE91). Carprofen is a non-steroidal antiinflammatory drug (NSAID) belonging to the group of 2-arylpropionic acids. Carprofen possesses analgesic and anti-inflammatory activity.

Carprofen Orion is a generic of Rimadyl vet, which has been authorised in the EU since 21 January 2003. Studies have demonstrated the satisfactory quality of Carprofen Orion, and its bioequivalence to the reference product Rimadyl vet.

The full indication is:

Dog: For alleviation of inflammation and pain in musculoskeletal and joint disorders and after surgical procedures.

For perioperative alleviation of pain and inflammation especially in orthopaedic and soft tissue (including ocular) procedures.

Cat: Perioperative alleviation of pain.

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.

[1] Summaries of opinion are published without prejudice to the Commission Decision.

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

[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.