10 November 2017
EMA/CVMP/673968/017
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

GALLIPRANT

International non-proprietary name (INN): grapiprant

On 9 November 2017, 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, GALLIPRANT tablets for dogs, intended for the treatment of pain associated with mild to moderate osteoarthritis in dogs. The applicant for this veterinary medicinal product is Aratana Therapeutics NV. The applicant is registered as an SME pursuant to the definition set out in Commission Recommendation 2003/361/EC.

GALLIPRANT is a non-steroidal, anti-inflammatory drug (NSAID), containing grapiprant (ATCvet code QM01AX92) as the active substance. Grapiprant is a non-cyclooxygenase NSAID and acts as a selective antagonist of the EP_4 receptor, a key prostaglandin E_2 receptor.

The benefit of GALLIPRANT is in the reduction of pain associated with mild to moderate osteoarthritis in dogs. The most common side effects are mild and generally transient gastrointestinal effects (vomiting, soft-formed faeces, diarrhoea, inappetence).

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-risk balance for GALLIPRANT 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.

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