

16 February 2018 EMA/CVMP/158720/2017 Committee for Medicinal Products for Veterinary Use

Summary of opinion¹ (post-authorisation)

Metacam

International non-proprietary name (INN): meloxicam

On 15 February 2018, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion², recommending the granting of a variation to the terms of the marketing authorisation for the veterinary medicinal product Metacam. The marketing authorisation holder for this veterinary medicinal product is Boehringer Ingelheim Vetmedica GmbH

Metacam is currently authorised for cattle, pigs, dogs, cats and horses. The variation concerns the addition of a new, non-food producing target species, the guinea pig, for the following indication: "Alleviation of mild to moderate post-operative pain associated with soft tissue surgery such as male castration".

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.

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.



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