6 December 2019
EMA/CVMP/622008/2019
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (post-authorisation)

Onsior

International non-proprietary name (INN): robenacoxib

On 5 December 2019, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion[2] recommending the granting of a variation to the terms of the marketing authorisation for the veterinary medicinal product Onsior. The marketing authorisation holder for this veterinary medicinal product is Elanco GmbH.

Onsior is currently authorised as tablets for cats, tablets for dogs and solution for injection for cats and dogs. The variation concerns the addition of a new therapeutic indication for the treatment of pain and inflammation associated with soft tissue surgery in dogs (tablets); in addition, this variation is to extend the period of administration for up to 2 days in dogs undergoing soft tissue surgery (solution for injection) and to amend the product information due to new clinical data in dogs.

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.

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