16 March 2018
EMA/CVMP/843508/2017
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (post-authorisation)

Onsior

International non-proprietary name (INN): robenacoxib

On 15 March 2018, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion[2], recommending the granting of variations to the terms of the marketing authorisation for the veterinary medicinal product Onsior. The marketing authorisation holder for this veterinary medicinal product is Elanco Europe Ltd.

Onsior is currently authorised for cats as tablets and solution for injection. The variations are to introduce the following changes:

- Addition of a new therapeutic indication: treatment of pain and inflammation associated with chronic musculo-skeletal disorders in cats (Onsior 6 mg tablets for cats);
- Significant modifications of the Summary of Product Characteristics: Interchangeable use of tablets and solution for injection - interchangeable use of Onsior 6 mg tablets and Onsior 20 mg/ml solution for injection for cats; Drug interaction robenacoxib and benazepril - concurrent use with furosemide and benazepril (Onsior 6 mg tablets and Onsior 20 mg/ml solution for injection in cats); Intravenous use of Onsior 20 mg/ml solution for injection in cats - overdose advice in case of accidental intravenous use.

In addition, several other amendments were implemented (editorial changes, updates to the product information requested by the Agency and updates consequent to the latest QRD template v.8.1).

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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