16 July 2020
EMA/94693/2021
Committee for Medicinal Products for Veterinary Use

Opinion of the Committee for Medicinal Products for Veterinary Use on the establishment of maximum residue limits

Procedure no: EMEA/V/MRL/003649/EXTN/0003

Name of the substance: Lidocaine (INN)

Basis for the opinion

Pursuant to Article 3 of Regulation (EC) No 470/2009 of 6 May 2009, Medical Ethics UK Ltd submitted to the European Medicines Agency on 24 April 2019 an application for the extension of maximum residue limits for lidocaine to bovine.

On 12 September 2019 the Committee for Medicinal Products for Veterinary Use adopted a list of questions to be addressed by the applicant. The response to the list of questions was submitted on 20 March 2020.

Recommendation

The Committee, having considered the application and having evaluated the response to the list of questions, recommends by consensus the extension of maximum residue limits for lidocaine in accordance with the following table:

Pharmacologically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions	Therapeutic classification
Lidocaine	Lidocaine	Bovine	150 µg/kg 200 µg/kg 1 µg/kg 200 µg/kg 30 µg/kg	Muscle Fat Liver Kidney Milk	Not applicable	Local anaesthetic

The Icelandic and Norwegian CVMP members agree with the above-mentioned recommendation of the Committee.

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The scientific conclusions of the Committee are presented in the European public MRL assessment report (EPMAR), provided in Annex I of this opinion.

The analytical method for monitoring of residues is appended to this opinion.

The present opinion is forwarded to the European Commission and to the applicant together with its appendices.

Annex I

European public MRL assessment report (EPMAR)