20 February 2020
EMA/CVMP/70565/2020
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/005009/FULL/0001

Name of the substance: Bupivacaine (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 22 June 2018 an application for the establishment of maximum residue limits for bupivacaine in porcine.

On 8 November 2018 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 17 April 2019.

Recommendation

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

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Pharmaco-logically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions	Therapeutic classification
Bupivacaine	NOT APPLICABLE	Porcine	No MRL required	NOT APPLICABLE	For use in piglets up to 7 days of age. For cutaneous and epilesional use only.	Local anaesthetic

The Norwegian CVMP member agrees with the above-mentioned recommendation of the Committee.

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