EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 May 2017
EMA/CVMP/255492/2017
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/004479/FULL/0001

Name of the substance: Bromelain

Basis for the opinion

Pursuant to Article 3 of Regulation (EC) No 470/2009 of 6 May 2009, Triveritas submitted to the European Medicines Agency on 20 June 2016 an application for the establishment of maximum residue limits for bromelain in porcine species.

On 10 November 2016 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 3 February 2017.

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 bromelain in accordance with the following table:

Pharmaco-logically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions	Therapeutic classification
Bromelain	NOT APPLICABLE	Porcine	No MRL required	NOT APPLICABLE	NO ENTRY	Antidiarrhoeal agents

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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)