EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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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/004828/FULL/0001

Name of the substance: Bambermycin (INN)

Basis for the opinion

Pursuant to Article 3 of Regulation (EC) No 470/2009 of 6 May 2009, Huvepharma N.V. submitted to the European Medicines Agency on 19 April 2017 an application for the establishment of maximum residue limits for bambermycin in rabbit.

On 7 September 2017 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 December 2018.

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 bambermycin in accordance with the following table:

Pharmaco-logically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions	Therapeutic classification
Bambermycin	NOT APPLICABLE	Rabbit	No MRL required	NOT APPLICABLE	For oral use only	Anti-infectious agent / Antibiotics

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.

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