15 July 2021
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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/EXTN/0002

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 03 December 2019 an application for the extension of maximum residue limits for bambermycin to chicken.

On 23 April 2020 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 18 December 2020.

On 18 March 2021, the Committee for Medicinal Products for Veterinary Use adopted an opinion recommending the extension of maximum residue limits for bambermycin to chicken tissues. Furthermore, with reference to Article 5 of Regulation (EC) No 470/2009 and in line with the criteria laid down in Commission Regulation (EU) 2017/880, the Committee agreed to extrapolate the conclusions to all poultry.

On 5 May 2021 the European Commission requested the Committee to reconsider its opinion of 18 March 2021 with a view to establishing numerical MRLs.

Recommendation

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

Pharmaco-logically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions	Therapeutic classification
Bambermycin	Flavophos-pholipol A	Poultry	100 µg/kg 100 µg/kg 3000 µg/kg 20000 µg/kg	Muscle Skin and fat in natural proportions Liver Kidney	Not for use in animals from which eggs are produced for human consumption	Anti-infectious agents / Antibiotics

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)