15 February 2018
EMA/CVMP/56181/2018
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/003517/EXTN/0003

Name of the substance: Paromomycin (INN)

Basis for the opinion

Pursuant to Article 3 of Regulation (EC) No 470/2009 of 6 May 2009, Huvepharma NV submitted to the European Medicines Agency on 24 June 2016 an application for the establishment of maximum residue limits for paromomycin to chicken eggs.

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 5 July 2017.

Recommendation

The Committee, having considered the application and having evaluated the response to the list of questions, recommends by consensus the establishment of a maximum residue limit for paromomycin in chicken eggs. Furthermore, and with reference to Article 5 of Regulation (EC) No 470/2009, the Committee agreed to extrapolate the maximum residue limit recommended in chicken eggs to eggs of other poultry species. Therefore, the Committee recommends by consensus the amendment of the entry for paromomycin in table 1 (Allowed substances) of the Annex to Regulation (EU) No 37/2010 as follows:

Pharmaco-logically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions	Therapeutic classification
Paromomycin	Paromomycin	All food producing species	500 µg/kg 1500 µg/kg 1500 µg/kg 200 µg/kg	Muscle Liver Kidney Eggs	For fin fish the muscle MRL relates to 'muscle and	Anti-infectious agents/Anti-biotics

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Pharmaco-logically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions	Therapeutic classification
					skin in natural proportions'. MRLs for liver and kidney do not apply to fin fish. Not for use in animals from which milk is produced for human consumption.	

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 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)