14 July 2016
EMA/CVMP/454065/2016
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/003158/EXTN/0003

Name of the substance: Gamithromycin (INN)

Basis for the opinion

Pursuant to Article 3 of Regulation (EC) No 470/2009, MERIAL submitted to the European Medicines Agency on 29 October 2015 an application for the extension of maximum residue limits for gamithromycin to ovine species.

On 17 March 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 13 May 2016.

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 gamithromycin in ovine species. Furthermore, and with reference to Article 5 of Regulation (EC) No 470/2009, the Committee agreed to extrapolate the maximum residue limits recommended in ovine species to all ruminants except bovine species.

Therefore, the Committee recommends by consensus the extension of the entry for gamithromycin in table 1 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
Gamithromycin	Gamithromycin	All ruminants except bovine	50 µg/kg 50 µg/kg 300 µg/kg 200 µg/kg	Muscle Fat Liver Kidney	Not for use in animals from which milk is produced for human consumption	Anti-infectious agents / Antibiotics

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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 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.

London, 14 July 2016

Signature on file

Dr David Murphy
Chair, on behalf of the CVMP

Annex I

European public MRL assessment report (EPMAR)