10 July 2014
EMA/CVMP/350420/2014
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/0002

Name of the substance: Gamithromycin (INN)

Basis for the opinion

Pursuant to Article 3 of Regulation (EC) No 470/2009 of 6 May 2009, Merial submitted to the European Medicines Agency on 9 July 2013 an application for the extension of maximum residue limits for gamithromycin to porcine species.

On 12 December 2013, 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 4 April 2014.

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 porcine species as follows:

Pharmaco-logically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions	Therapeutic classification
Gamithromycin	Gamithromycin	Porcine	100 µg/kg 100 µg/kg 100 µg/kg 300 µg/kg	Muscle Skin and fat in natural proportions Liver Kidney	NO ENTRY	Anti-infectious agents / Antibiotics

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The Icelandic 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, 10 July 2014

Signature on file

Dr. A. Holm
Chair, on behalf of the CVMP

Annex I

European public MRL assessment report (EPMAR)