10 July 2014
EMA/CVMP/380415/2014
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: EU/12/199/PFZ

Name of the substance: Tulathromycin (INN)

Basis for the opinion

Pursuant to Article 3 of Regulation (EC) No 470/2009 of 6 May 2009, Pfizer Animal Health SA submitted to the European Medicines Agency on 2 February 2012 an application for the modification of maximum residue limits for tulathromycin in bovine and porcine species.

On 14 June 2012 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 11 January 2013.

On 10 October 2013 the Committee for Medicinal Products for Veterinary Use adopted an opinion recommending provisional maximum residue limits for tulathromycin in bovine and porcine species and 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 response to the list of questions after the establishment of provisional maximum residue limits, recommends by consensus the removal of the provisional status of the maximum residue limits for tulathromycin in bovine and porcine tissues, and the modification of the entry for tulathromycin in Table 1 (Allowed substances) of the Annex to Regulation (EU) No 37/2010 as follows:

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Pharmaco-logically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions	Therapeutic classification
Tulathromy-cin	(2R,3S,4R,5R,8R,10R, 11R,12S,13S,14R)-2-ethyl-3,4,10,13-tetrahydroxy-3,5,8,10,12,14-hexamethyl-11-[[3,4,6-trideoxy-3-(dimethylamino)-ß-D-xylo-hexopyranosyl]oxy]-1-oxa-6-azacyclopentadecan-15-one expressed as tulathromycin equivalents	Bovine	300 µg/kg 200 µg/kg 4500 µg/kg 3000 µg/kg	Muscle Fat Liver Kidney	Not for use in animals from which milk is produced for human consumption	Anti-infectious agents/ Antibiotics
		Porcine	800 µg/kg 300 µg/kg 4000 µg/kg 8000 µg/kg	Muscle Skin and fat in natural propor-tions Liver Kidney		

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)