EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

18 July 2013
EMA/CVMP/440151/2013
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/09/166/INT

Name of the substance: Tildipirosin (INN)

Basis for the opinion

Pursuant to Article 6 of Regulation (EEC) No 2377/90 of 26 June 1990, as amended, Intervet International BV submitted to the European Medicines Agency on 5 March 2009 an application for the establishment of maximum residue limits for tildipirosin in bovine and porcine species.

On 17 June 2009 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 10 November 2009.

On 10 December 2009 the Committee for Medicinal Products for Veterinary Use adopted an opinion recommending the establishment of provisional maximum residue limits for tildipirosin in bovine, caprine and porcine species and adopted a list of questions to be addressed by the applicant.

Commission Regulation (EC) No 759/2010[1] of 24 August 2010 established provisional maximum residue limits for tildipirosin in bovine, caprine and porcine species, which expired on 1 January 2012.

The response to the list of questions further to the establishment of provisional MRLs was submitted on 15 June 2011.

On 15 September 2011 the Committee adopted an opinion recommending the establishment of maximum residue limits for tildipirosin in bovine, caprine and porcine species.

On 25 October 2011 the European Commission requested the Committee to reconsider its opinion of 15 September 2011 and to amend the part of the opinion that includes an MRL for the injection site in the “Other provisions” of Table I of the Annex to Commission Regulation (EU) 37/2010.

[1] O.J. L223/39 of 25.08.2010

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On 8 December 2011 the Committee adopted a revised opinion recommending the establishment of maximum residue limits for tildipirosin in bovine, caprine and porcine species, maintaining its previous recommendation.

On 5 October 2012 the European Commission requested the Committee to reconsider its opinion of 8 December 2011, in particular focusing on the provisions relating to the injection site and the feasibility of residue controls.

Recommendation

The Committee, having considered the application and having considered the requests from the Commission, recommends by consensus the establishment of maximum residue limits for tildipirosin in accordance with the following table:

Pharmaco-logically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions	Therapeutic classification
Tildipirosin	Tildipirosin	Bovine, caprine	400 µg/kg 200 µg/kg 2000 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	1200 µg/kg 800 µg/kg 5000 µg/kg 10000 µg/kg	Muscle Skin and fat in natural proportions Liver Kidney	NO ENTRY	

The Icelandic and Norwegian CVMP members agree 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, 18 July 2013

Signature on file

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

Annex I

European public MRL assessment report (EPMAR)