5 June 2014
EMA/CVMP/293995/2014
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/10/173/MER

Name of the substance: Eprinomectin (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 30 April 2010 an application for the extension of maximum residue limits for eprinomectin to ovine species.

On 15 September 2010 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 November 2011.

On 13 April 2012 the Committee for Medicinal Products for Veterinary Use adopted an opinion recommending the establishment of provisional maximum residue limits for eprinomectin in ovine species and the extrapolation of the conclusion to caprine species, and adopted a list of questions to be addressed by the applicant.

Commission Regulation (EU) No 116/2013[1] of 8 February 2013 established provisional maximum residue limits for eprinomectin in ovine and caprine species. The provisional maximum residue limits expire on 1 July 2014.

Merial submitted, on 4 April 2014, the responses to the list of questions further to the establishment of provisional maximum residue limits for ovine and caprine species.

Recommendation

The Committee, having considered the response to the list of questions after the establishment of the provisional maximum residue limits, and in accordance with Article 14(4) of Regulation (EC) 470/2009, recommends by consensus the extension of the time period applying to the provisional maximum residue limits, in accordance with the following table:

[1] O.J. L38/14 of 09.02.2013

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Pharmaco-logically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions	Therapeutic classification
Eprinomectin	Eprinomectin B1a	Bovine	50 µg/kg 250 µg/kg 1500 µg/kg 300 µg/kg 20 µg/kg	Muscle Fat Liver Kidney Milk	No entry	Antiparasitic agents/Agents acting against endo- and ectoparasites
		Ovine, caprine	50 µg/kg 250 µg/kg 1500 µg/kg 300 µg/kg 20 µg/kg	Muscle Fat Liver Kidney Milk	Provisional maximum residue limits expire on 30 June 2016	

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 preliminary analytical methods for monitoring of residues are appended to this opinion.

The present opinion is forwarded to the European Commission and to the applicant together with its appendices.

London, 5 June 2014

Signature on file

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

Annex I

European public MRL assessment report (EPMAR)