10 December 2015
EMA/CVMP/779112/2015
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 establishment of maximum residue limits for eprinomectin in 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 were set to 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.

On 5 June 2014 the Committee for Medicinal Products for Veterinary Use adopted an opinion recommending the extension of provisional maximum residue limits for eprinomectin to ovine and caprine species and adopted a further list of questions to be addressed by the applicant. The response to the list of questions was submitted on 28 August 2015.

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

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

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 eprinomectin in ovine and caprine species further to the establishment of provisional maximum residue limits. Furthermore, and with reference to Article 5 of Regulation (EC) No 470/2009, the Committee agreed to extrapolate the maximum residue limits established in bovine, ovine and caprine species to all ruminants. Therefore the Committee recommends by consensus the modification of the entry in Regulation (EU) No 37/2010 for eprinomectin in accordance with the following table:

Pharmaco-logically active substance	**Marker residue**	**Animal species**	**MRLs**	**Target tissues**	**Other provisions**	**Therapeutic classification**
Eprinomectin	Eprinomectin B1a	All ruminants	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

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 December 2015

Signature on file

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

Annex I

European public MRL assessment report (EPMAR)