15 January 2014
EMA/CVMP/741512/2013-Rev.1
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/ART27/11/191/IMB

Name of the substance: Closantel (INN)

Basis for the opinion

Pursuant to Article 27(2) of Regulation (EC) No 470/2009 of 6 May 2009, Irish Medicines Board submitted to the European Medicines Agency on 19 August 2011 a request for an opinion on the extrapolation of maximum residue limits for closantel to bovine and ovine milk.

On 10 November 2011, the Committee for Medicinal Products for Veterinary Use adopted an opinion recommending the extrapolation of the maximum residue limits for closantel to bovine and ovine milk. The maximum residue limit recommended for milk was provisional pending resolution of outstanding issues relating to the analytical method as reflected in the list of questions adopted with the recommendation. The response to the list of questions was submitted on 6 September 2013.

On 12 December 2013 the Committee adopted an opinion recommending the extrapolation of the maximum residue limits for closantel to bovine and ovine milk further to the provisional maximum residue limits in milk.

On 8 January 2014, the European Commission requested the review of the opinion in order to increase comprehensibility and consistency in particular with regard to the assessment of the outstanding issues identified at the time of the establishment of the provisional maximum residue limit.

Recommendation

The Committee, having considered the response to the list of questions after the establishment of the provisional maximum residue limits in milk and having reviewed the request from the Commission, confirms the maximum residue limits extrapolated to bovine and ovine milk and, recommends by consensus the removal of the provisional status of the maximum residue limits in milk for closantel.

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It is therefore recommended to the amend the entry for closantel in Table 1 (Allowed substances) of the Annex to Commission Regulation (EU) No 37/2010 in accordance with the following table:

Pharmaco-logically active substance	**Marker residue**	**Animal species**	**MRLs**	**Target tissues**	**Other provisions**	**Therapeutic classification**
Closantel	Closantel	Bovine	1000 µg/kg 3000 µg/kg 1000 µg/kg 3000 µg/kg 45 µg/kg	Muscle Fat Liver Kidney Milk	NO ENTRY	Antiparasitic agents/Agents against endoparasites
		Ovine	1500 µg/kg 2000 µg/kg 1500 µg/kg 5000 µg/kg 45 µg/kg	Muscle Fat Liver Kidney Milk		

The Norwegian 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, 15 January 2014

Signature on file

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

Annex I

European public MRL assessment report (EPMAR)