10 November 2011
EMA/CVMP/846763/2011
Veterinary Medicine and Product Data Management

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

Recommendation

The Committee, having considered the request, recommends by consensus the extrapolation of the maximum residue limits for closantel to bovine and ovine milk and the amendment of table 1 of the Annex to 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	Muscle Fat Liver Kidney		Antiparasitic agents/Agents against endoparasites
		Ovine	1500 µg/kg 2000 µg/kg 1500 µg/kg 5000 µg/kg	Muscle Fat Liver Kidney		
		Bovine, ovine	45 µg/kg	Milk	Provisional MRL expire on 1 January 2014	

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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 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 November 2011

Signature on file

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

Annex I

European public MRL assessment report (EPMAR)