EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 December 2013
EMA/CVMP/672931/2013
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/ART27/11/192/IMB

Name of the substance: Rafoxanide (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 an application for the extrapolation of maximum residue limits for rafoxanide in bovine and ovine milk.

On 10 November 2011 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 6 September 2013.

Recommendation

The Committee, having considered the application and having evaluated the response to the list of questions, recommends by consensus the extrapolation of maximum residue limits for rafoxanide to milk and the amendment of the entry for rafoxanide in table 1 of the Annex to Regulation (EU) No 37/2010 in accordance with the following table:

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Pharmaco-logically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions	Therapeutic classification
Rafoxanide	Rafoxanide	Bovine	30 µg/kg 30 µg/kg 10 µg/kg 40 µg/kg	Muscle Fat Liver Kidney	NO ENTRY	Antiparasitic agents/Agents against endoparasites
		Ovine	100 µg/kg 250 µg/kg 150 µg/kg 150 µg/kg	Muscle Fat Liver Kidney		
		Bovine, ovine	10 µg/kg	Milk	Provisional MRL expire on 1 January 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 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, 12 December 2013

Signature on file

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

Annex I

European public MRL assessment report (EPMAR)