9 October 2014
EMA/CVMP/587830/2014
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: EMEA/V/MRL/003298/MODF/0004

Name of the substance: Aluminium salicylate, basic (INN)

Basis for the opinion

Pursuant to Article 3 of Regulation (EC) No 470/2009 of 6 May 2009, COOPHAVET submitted to the European Medicines Agency on 30 January 2013 an application for the modification of maximum residue limits for aluminium salicylate, basic to allow the establishment of a maximum residue limit in bovine milk.

On 13 June 2013 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 10 July 2014.

Recommendation

The Committee, having considered the application and having evaluated the response to the list of questions, recommends by consensus the modification of the maximum residue limit classification for aluminium salicylate, basic with the establishment of provisional maximum residue limits, 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
Aluminium salicylate, basic	Salicylic acid	Bovine, caprine, *Equidae*, rabbit	200 µg/kg 500 µg/kg 1500 µg/kg 1500 µg/kg	Muscle Fat Liver Kidney	Provisional MRLs expire on 31 December 2016.	Antidiarrhoeal and intestinal anti-inflammatory agents
		Bovine, caprine, *Equidae*	9 µg/kg	Milk		
	NOT APPLICABLE	All food producing species except bovine, caprine, *equidae*, rabbit and fin fish	No MRL required	NOT APPLICABLE	For topical use only.	

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, 9 October 2014

Signature on file

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

Annex I

European public MRL assessment report (EPMAR)