16 May 2012
EMA/CVMP/804330/2011- 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/11/187/ELY

Name of the substance: Monensin (INN)

Basis for the opinion

Pursuant to Article 3 of Regulation (EC) No 470/2009 of 6 May 2009, Eli Lilly and Company Limited submitted to the European Medicines Agency on 1 June 2011 an application for the modification of maximum residue limits for monensin in bovine species.

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 11 January 2012.

On 8 March 2012 the Committee adopted an opinion recommending the modification of the maximum residue limits for monensin in bovine species.

On 23 April 2012 the European Commission requested a review of the opinion in order to improve the clarity of the document.

Recommendation

The Committee, having considered the application and reviewed the request from the Commission, recommends by consensus the modification of maximum residue limits for monensin and the amendment of the entry for monensin in table 1 of the Annex to Regulation (EU) No 37/2010, in accordance with the following table:

Pharmacologically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions	Therapeutic classification
Monensin	Monensin A	Bovine	2 µg/kg 10 µg/kg 50 µg/kg 10 µg/kg 2 µg/kg	Muscle Fat Liver Kidney Milk	NO ENTRY	Anti-infectious agents/ Antibiotics

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

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 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, 16 May 2012

Signature on file

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

Annex I

European public MRL assessment report (EPMAR)