10 January 2013
EMA/CVMP/14468/2013
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/12/200/WAR

Name of the substance: Manganese carbonate (INN)

Basis for the opinion

Pursuant to Article 3 of Regulation (EC) No 470/2009 of 6 May 2009, Warburton Technology submitted to the European Medicines Agency on 3 February 2012 an application for the extension of maximum residue limits for manganese carbonate in bovine species to include parenteral use.

On 12 July 2012 the Committee adopted an opinion recommending the extension of maximum residue limits for manganese carbonate to include parenteral use.

On 29 November 2012 the European Commission requested the Committee to review the wording of its opinion with a view to providing clarification on a number of points.

Recommendation

The Committee, having considered the application and the request from the European Commission, recommends, by consensus, the extension of maximum residue limits for manganese carbonate to include parenteral use, 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
Manganese carbonate	NOT APPLICABLE	All food producing species	NO MRL REQUIRED	NOT APPLICABLE	NO ENTRY	Alimentary tract and metabolism / mineral supplements

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8447
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 present opinion is forwarded to the European Commission and to the applicant together with its appendices.

London, 10 January 2013

Signature on file

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

Annex I

European public MRL assessment report (EPMAR)