EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

16 May 2012
EMA/CVMP/219741/2012
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/11/195/NOV

Name of the substance: Monepantel (INN)

Basis for the opinion

Pursuant to Article 3 of Regulation (EC) No 470/2009 of 6 May 2009, Novartis Animal Health Inc submitted to the European Medicines Agency on 30 August 2011 an application for the extension of maximum residue limits for monepantel to ovine milk.

On 12 January 2012 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 16 February 2012.

Recommendation

The Committee, having considered the application and having evaluated the response to the list of questions, recommends by consensus the establishment of maximum residue limits for monepantel in ovine and caprine 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
Monepantel	Monepantel sulfone	Ovine, caprine	700 µg/kg 7000 µg/kg 5000 µg/kg 2000 µg/kg 170 µg/kg	Muscle Fat Liver Kidney Milk		Antiparasitic agents/Agents against endoparasites

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)