EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

19 May 2016
EMA/CVMP/322539/2016
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/003200/EXTN/0003

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 UK Ltd submitted to the European Medicines Agency on 15 January 2015 an application for the extension of maximum residue limits for monepantel to bovine species.

On 4 June 2015 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 17 November 2015. At the same time, the European Medicines Agency was informed that, following acquisition of Novartis Animal Health, the application had been taken over by Eli Lilly and Company Limited.

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 accordance with the following table:

Pharmaco-logically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions	Therapeutic classification
Monepantel	Monepantel sulfone	Bovine	300 µg/kg 7000 µg/kg 2000 µg/kg 1000 µg/kg	Muscle Fat Liver Kidney	Not for use in animals producing milk for human consumption	Antiparasitic agents / Agents (acting) against endoparasites

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The Icelandic CVMP member agrees 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, 19 May 2016

Signature on file

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

Annex I

European public MRL assessment report (EPMAR)