8 March 2012
EMA/CVMP/78444/2012
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/10/183/BAY

Name of the substance: Phoxim (INN)

Basis for the opinion

Pursuant to Article 3 of Regulation (EC) No 470/2009 of 6 May 2009, Bayer Animal Health GmbH submitted to the European Medicines Agency on 13 December 2010 an application for the extension of maximum residue limits for phoxim to bovine species and, at the same time, the modification of the existing MRLs to produce a harmonised set of MRLs in all species for which MRLs are established.

On 4 May 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 9 December 2011.

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Recommendation

The Committee, having considered the application and having evaluated the response to the list of questions, recommends by consensus the modification of the existing MRLs for phoxim, the extension of the MRLs to bovine species, the extrapolation of the MRLs to all food producing species except fin fish, and the amendment of table 1 of the Annex to Commission Regulation (EU) 37/2010, as follows:

Pharmaco-logically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions	Therapeutic classification
Phoxim	Phoxim	All food producing species except fin fish	25 µg/kg 550 µg/kg 50 µg/kg 30 µg/kg 60 µg/kg	Muscle Fat Liver Kidney Eggs	For porcine and poultry species the fat MRL relates to 'skin and fat in natural proportions'. Not for use in animals from which milk is produced for human consumption	Antiparasitic agents/Agents against ectoparasites

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, 8 March 2012

Signature on file

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

Annex I

European Public MRL Assessment Report (EPMAR)