10 November 2011
EMA/CVMP/848524/2011
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/ART27/11/194/IMB

Name of the substance: Nitroxinil (INN)

Basis for the opinion

Pursuant to Article 27 of Regulation (EC) No 470/2009 of 6 May 2009, Ireland submitted to the European Medicines Agency on 30 August 2011 a request for an opinion on the extrapolation of maximum residue limits for nitroxinil to bovine and ovine milk.

Recommendation

The Committee, having considered the request, recommends by consensus the extrapolation of the maximum residue limits for nitroxinil to bovine and ovine 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
Nitroxinil	Nitroxinil	Bovine, ovine	400 µg/kg 200 µg/kg 20 µg/kg 400 µg/kg 20 µg/kg	Muscle Fat Liver Kidney Milk		Antiparasitic agents/Agents against endoparasites

The Icelandic and Norwegian CVMP members agree with the above-mentioned recommendation of the Committee.

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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, 10 November 2011

Signature on file

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

Annex I

European public MRL assessment report (EPMAR)