EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

13 April 2012
EMA/CVMP/183880/2012
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/11/198/HUV

Name of the substance: Diclazuril (INN)

Basis for the opinion

Pursuant to Article 3 of Regulation (EC) No 470/2009 of 6 May 2009, Huvepharma NV submitted to the European Medicines Agency on 27 October 2011 an application for the extension of maximum residue limits for diclazuril to poultry.

Recommendation

The Committee, having considered the application recommends, by consensus the establishment of maximum residue limits for diclazuril in poultry and the amendment of table 1 of the Annex to Commission Regulation (EU) No 37/2010, as follows:

Pharmaco-logically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions	Therapeutic classification
Diclazuril	Diclazuril	Poultry	500 µg/kg 500 µg/kg 1500 µg/kg 1000 µg/kg	Muscle Skin and fat in natural proportions Liver Kidney	Not for use in animals from which eggs are produced for human consumption	Antiparasitic agents/Agents acting against protozoa

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, 13 April 2012

Signature on file

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

Annex I

European public MRL assessment report (EPMAR)