8 May 2014
EMA/CVMP/239251/2014
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/002860/FULL/0002

Name of the substance: Clodronic acid (in the form of disodium salt)

Basis for the opinion

Pursuant to Article 3 of Regulation (EC) No 470/2009 of 6 May 2009, Dechra Limited submitted to the European Medicines Agency on 26 November 2013 an application for the establishment of maximum residue limits for clodronoc acid (in the form of disodium salt) in horses.

Recommendation

The Committee, having considered the application, concluded that the establishment of maximum residue limits for clodronic acid (in the form of disodium salt) in *Equidae* is not necessary for the protection of human health and therefore recommends by consensus the inclusion of clodronic acid (in the form of disodium salt) in table 1 of the Annex to Regulation (EU) No 37/2010 in accordance with the following table:

Pharmacologically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions	Therapeutic classification
Clodronic acid (in the form of disodium salt)	NOT APPLICABLE	*Equidae*	No MRL required	NOT APPLICABLE	Not for use in animals from which milk is produced for human consumption	Musco-skeletal system / drugs for treatment of bone diseases

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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 present opinion is forwarded to the European Commission and to the applicant together with its appendices.

London, 8 May 2014

Signature on file

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

Annex I

European public MRL assessment report (EPMAR)