



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

10 July 2014
EMA/CVMP/347690/2014
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/003802/FULL/0001

Name of the substance: Hexaflumuron (INN)

Basis for the opinion

Pursuant to Article 3 of Regulation (EC) No 470/2009 of 6 May 2009, PHARMAQ AS submitted to the European Medicines Agency on 29 May 2013 an application for the establishment of maximum residue limits for hexaflumuron in fin fish.

On 10 October 2013, 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 4 April 2014.

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 hexaflumuron in accordance with the following table:

Pharmacologically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions	Therapeutic classification
Hexaflumuron	Hexaflumuron	Fin fish	500 µg/kg	Muscle and skin in natural proportions	NO ENTRY	Antiparasitic agents / Agents (acting) against ectoparasites



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, 10 July 2014

Signature on file

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

Annex I

European public MRL assessment report ([EPMAR](#))