EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

9 November 2017
EMA/CVMP/698003/2017
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/003141/EXTN/0004

Name of the substance: Eprinomectin (INN)

Basis for the opinion

Pursuant to Article 3 of Regulation (EC) No 470/2009 of 6 May 2009, Farmacologia en Aquacultura Veterinaria FAV S.A. submitted to the European Medicines Agency on 16 May 2017 an application for the extension of maximum residue limits for eprinomectin to fin fish.

Recommendation

The Committee, having considered the application, recommends by consensus the extension of maximum residue limits for eprinomectin to fin fish. Furthermore, and with reference to Article 5 of Regulation (EC) No 470/2009, the Committee considers that the MRLs established in ruminants can be extrapolated to horses and rabbits in accordance with the following table:

Pharmaco-logically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions	Therapeutic classification
Eprinomectin	Eprinomectin B1a	All ruminants, *Equidae*	50 µg/kg 250 µg/kg 1500 µg/kg 300 µg/kg 20 µg/kg	Muscle Fat Liver Kidney Milk	No entry	Antiparasitic agents/Agents acting against endo- and ectoparasites
		Fin fish	50 µg/kg	Muscle and skin in natural proportions		
		Rabbits	50 µg/kg 250 µg/kg 1500 µg/kg 300 µg/kg	Muscle Fat Liver Kidney		

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The Norwegian 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.

Annex I

European public MRL assessment report (EPMAR)