20 April 2023
EMA/CVMP/152100/2023
Committee for Veterinary Medicinal Products

Opinion of the Committee for Veterinary Medicinal Products on the establishment of maximum residue limits

Procedure no: EMEA/V/MRL/003450/EXPL/0005

Name of the substance: Rafoxanide (INN)

Basis for the opinion

Pursuant to Article 27(2) of Regulation (EC) No 470/2009 of 6 May 2009, Ireland submitted to the European Medicines Agency on 20 February 2023 a request for the extrapolation of maximum residue limits for rafoxanide to bovine and ovine milk.

Recommendation

The Committee, having considered the request, recommends by consensus the extrapolation of maximum residue limits for rafoxanide to bovine and ovine milk. Furthermore, with reference to Article 5 of Regulation (EC) No 470/2009 and in line with the criteria laid down in Commission Regulation (EU) 2017/880, the Committee agreed to extrapolate the maximum residue limits in bovine tissues and milk to all ruminants except ovine, for which (higher) MRLs are already established. Therefore, the Committee recommends the extrapolation of maximum residue limits for rafoxanide in accordance with the following table:

Pharmaco-logically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions	Therapeutic classification
Rafoxanide	Rafoxanide	All ruminants except ovine	30 µg/kg 30 µg/kg 10 µg/kg 40 µg/kg 10 µg/kg	Muscle Fat Liver Kidney Milk	NO ENTRY	Antiparasitic agents/Agents (acting) against endoparasites
		Ovine	100 µg/kg 250 µg/kg 150 µg/kg 150 µg/kg 10 µg/kg	Muscle Fat Liver Kidney Milk		

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 Ireland together with its appendices.

Annex I

European public MRL assessment report (EPMAR)