18 February 2016
EMA/CVMP/89149/2016
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/002993/FULL/0002

Name of the substance: Hydrocortisone aceponate (INN)

Basis for the opinion

Pursuant to Article 3 of Regulation (EC) No 470/2009 of 6 May 2009, Virbac S.A. submitted to the European Medicines Agency on 26 February 2014 an application for the establishment of maximum residue limits for hydrocortisone aceponate in bovine species.

On 10 July 2014, 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 12 January 2015.

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 hydrocortisone aceponate in bovine species. Furthermore, and in accordance with Article 5 of Regulation (EC) No 470/2009, the Committee agreed to extrapolate the maximum residue limits recommended in bovine species to all ruminants and *Equidae*.

Therefore, the Committee recommends by consensus the establishment of maximum residue limits for hydrocortisone aceponate in accordance with the following table:

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Pharmaco-logically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions	Therapeutic classification
Hydrocortisone aceponate	Sum of hydrocortisone and its esters after alkaline hydrolysis expressed as hydrocortisone	All ruminants, *Equidae*	10 µg/kg	Milk	For intramammary use only.	Corticosteroids
	NOT APPLICABLE	All ruminants, *Equidae*	No MRL required for all tissues except milk	NOT APPLICABLE		

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, 18 February 2016

Signature on file

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

Annex I

European Public MRL Assessment Report (EPMAR)