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EMA/CVMP/101968/2019
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/005010/FULL/0001

Name of the substance: ciclesonide (INN)

Basis for the opinion

Pursuant to Article 3 of Regulation (EC) No 470/2009 of 6 May 2009, Boehringer Ingelheim Vetmedica GmbH submitted to the European Medicines Agency on 26 February 2018 an application for the establishment of maximum residue limits for ciclesonide in *Equidae*.

On 19 July 2018 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 28 September 2018.

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 ciclesonide in accordance with the following table:

Pharmacologically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions	Therapeutic classification
Ciclesonide	The sum of ciclesonide and desisobutyryl-ciclesonide, measured as desisobutyryl-	<i>Equidae</i>	0.6 µg/kg 4 µg/kg 0.6 µg/kg 0.6 µg/kg	Muscle Fat Liver Kidney	Not for use in animals from which milk is produced for	Corticoides / Glucocorticoides



Pharmaco- logically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions	Therapeutic classification
	ciclesonide after hydrolysis of ciclesonide to desisobutyryl-ciclesonide				human consumption	

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.