



22 February 2019  
EMA/CVMP/113233/2019  
Committee for Medicinal Products for Veterinary Use

## MRL summary opinion<sup>1</sup>

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# Ciclesonide

## *Equidae*

On 21 February 2019, the Committee for Medicinal Products for Veterinary Use adopted an opinion<sup>2</sup> recommending the inclusion of ciclesonide in *Equidae* in Table 1 (Allowed substances) of the Annex to Commission Regulation (EU) No 37/2010 of 22 December 2009, 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-ciclesonide after hydrolysis of ciclesonide to desisobutyryl-ciclesonide	<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 human consumption	Corticoides / Glucocorticoides

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<sup>1</sup> Summaries of opinion are published without prejudice to the Commission Decision.

<sup>2</sup> Applicants may request re-examination of any CVMP opinion, provided they notify the European Medicines Agency in writing of their intention to request such re-examination within 15 days of receipt of the opinion

