10 July 2014
EMA/CVMP/339063/2014
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/002964/EXTN/0004

Name of the substance: Methylprednisolone (INN)

Basis for the opinion

Pursuant to Article 3 of Regulation (EC) No 470/2009 of 6 May 2009, Zoetis Belgium SA submitted to the European Medicines Agency on 22 January 2014 an application for the extension of maximum residue limits for methylprednisolone to *Equidae*.

Recommendation

The Committee, having considered the application, recommends by consensus the establishment of maximum residue limits for methylprednisolone in *Equidae*.

Furthermore, and with reference to Article 5 of Regulation (EC) No 470/2009, the Committee agreed to extrapolate the maximum residue limit established in bovine milk to horse milk, and therefore recommends by consensus to extend the entry for methylprednisolone in table 1 of the Annex to Regulation (EU) No 37/2010 as follows:

Pharmaco-logically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions	Therapeutic classification
Methyl-prednisolone	Methyl-prednisolone	*Equidae*	10 µg/kg 10 µg/kg 10 µg/kg 10 µg/kg 2 µg/kg	Muscle Fat Liver Kidney Milk	NO ENTRY	Corticoides / Glucocorticoides

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8447
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

The Icelandic 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.

London, 10 July 2014

Signature on file

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

Annex I

European public MRL assessment report (EPMAR)