13 October 2011
EMA/CVMP/687242/2011
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: EU/ART11/11/188/VMD

Name of the substance: Altrenogest (INN)

Basis for the opinion

Pursuant to Article 11 of Regulation (EC) No 470/2009 of 6 May 2009, the United Kingdom, as a result of new information, submitted to the European Medicines Agency on 6 June 2011, a request to issue a new opinion on the maximium residue limits for altrenogest.

Recommendation

The Committee, having considered the United Kingdom's request, recommends by consensus the modification of maximum residue limits for altrenogest in accordance with the following table:

Pharmaco-logically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions	Therapeutic classification
Altrenogest	Altrenogest	Porcine	4 µg/kg 2 µg/kg	Skin and fat Liver	For zootechnical use only and in accordance with the provisions of Directive 96/22/EC.	Agents acting on the reproductive system
		Equidae	4 µg/kg 4 µg/kg	Fat Liver		

The Icelandic and Norwegian CVMP members agree with the above-mentioned recommendation of the Committee.

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 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, 13 October 2011

Signature on file

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

Annex I

European public MRL assessment report (EPMAR)