EMA/CVMP/762138/2009

OPINION OF THE COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE ON THE ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS

PROCEDURE No EU/09/166/INT

Name of the substance: Tildipirosin (INN)

Basis for the opinion

Pursuant to Article 6 of Council Regulation (EEC) No 2377/90 of 26 June 1990, as amended, Intervet International BV submitted to the European Medicines Agency on 5 March 2009, an application for the establishment of maximum residue limits for tildipirosin in bovine and porcine species.

On 17 June 2009 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 10 November 2009.

Recommendation

The Committee, having considered the application and having evaluated the response to the List of Questions, recommends by consensus the establishment of provisional maximum residue limits for tildipirosin in accordance with the table shown overleaf:

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Pharmaco-logically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions	Therapeutic classification
Tildipirosin	Tildipirosin	Bovine Caprine	400 µg/kg 200 µg/kg 2000 µg/kg 3000 µg/kg	Muscle Fat Liver Kidney	Not for use in animals from which milk is produced for human consumption. The MRL for muscle does not apply to the injection site, where residue levels should not exceed 11500 µg/kg. Provisional MRLs expire on 1 January 2012.	Macrolide
		Porcine	1200 µg/kg 800 µg/kg 5000 µg/kg 10000 µg/kg	Muscle Skin+fat Liver Kidney	The MRL for muscle does not apply to the injection site, where residue levels should not exceed 7500 µg/kg. Provisional MRLs expire on 1 January 2012.	

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 preliminary 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 December 2009

Signature on file

Dr. G. Moulin
Chairman, on behalf of the CVMP

ANNEX I

European Public MRL Assessment Report
(EPMAR)