15 September 2011
EMA/CVMP/165867/2011-Rev.1
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/08/163/NOV

Name of the substance: Monepantel (INN)

Basis for the opinion

Pursuant to Article 6 of Council Regulation (EEC) No 2377/90 of 26 June 1990, as amended, Novartis Animal Health submitted to the European Medicines Agency (the Agency) on 31 January 2008 an application for the establishment of maximum residue limits for monepantel in ovine species.

On 12 November 2008 the Committee for Medicinal Products for Veterinary Use (CVMP) adopted an opinion recommending the establishment of maximum residue limits for monepantel for ovine species and the establishment of provisional maximum residue limits for caprine species and adopted a list of questions concerning caprine species to be addressed by the applicant. Commission Regulation (EC) No 478/20091 of 8 June 2009 established maximum residue limits for ovine species and provisional maximum residue limits for caprine species, which expired on 1 January 2011.

On 12 July 2010 Novartis Animal Health requested an extension to the expiry date for provisional MRLs in caprine species in order to complete the scientific studies requested by the Committee. On 15 September 2010 the Committee for Medicinal Products for Veterinary Use adopted an opinion recommending the extension to the expiry date for the provisional MRLs in caprine species to 1 January 2012.

The response to the list of questions further to the establishment of provisional maximum residue limits was submitted to the Agency on 9 December 2010.

On 9 March 2011 the CVMP adopted an opinion recommending the establishment of maximum residue limits for monepantel in caprine species.

On 12 July the European Commission requested a reconsideration of the opinion of 9 March 2011 to review the possibility of extrapolating the recommended maximum residue limits to ovine milk, all ruminants, monogastric food-producing animals, poultry (and eggs), fin fish and honey.

[1] O.J. L144/17 of 09.06.2009

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Recommendation

The Committee, having considered the application, evaluated the response to the list of questions further to the establishment of provisional MRLs in caprine species and reviewed the request from the Commission recommends by consensus, the amendment of the entry for monepantel in table 1 of the Annex to Commission Regulation (EU) No 37/2010 of 22 December 2010, in accordance with the following table:

Pharmaco-logically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions	Therapeutic classification
Monepantel	Monepantel -sulfone	Ovine, caprine	700 µg/kg 7000 µg/kg 5000 µg/kg 2000 µg/kg	Muscle Fat Liver Kidney	Not for use in animals producing milk for human consumption	Antiparasitic agents/Agents acting against endoparasites

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 present opinion is forwarded to the European Commission, and to the applicant.

London, 15 September 2011

Signature on file

Dr A. Holm
Chair, on behalf of the CVMP

Annex I

European public MRL assessment report (EPMAR)