15 September 2010
EMA/CVMP/569128/2010
Veterinary Medicine and Product Data Management

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

Basis for the opinion

Pursuant to Article 7 of Council Regulation (EEC) No 2377/90 of 26 June 1990, as amended, Novartis Animal Health submitted to the EMEA on 31 January 2008 an application for the establishment of maximum residue limits for monepantel in ovine species. On 18 March 2008 Novartis requested an extrapolation of the maximum residue limits for ovine species to caprine 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 478/2009[1] of 8 June 2009 established maximum residue limits for ovine species and provisional maximum residue limits for caprine species, which expire on 1 January 2011.

Novartis Animal Health requested on 12 July 2010 the extension to the expiration date for provisional MRLs in order to complete the scientific studies requested by the Committee.

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

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Recommendation

The Committee, having considered the request and in accordance with Article 14(4) of Regulation 470/2009 recommends, by consensus, the extension to the expiration date for provisional maximum residue limits in accordance with the following table:

Pharmaco-logically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions	Therapeutic classification
Monepantel	Monepantel-sulfone	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. Provisional MRLs expire on 1.1.2012	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 2010

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

Annex I

European public MRL assessment report (EPMAR)