9 February 2012
EMA/CVMP/63588/2012
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/07/159/CHV

Name of the substance: Sodium salicylate (INN)

Basis for the opinion

In accordance with Article 6 of Council Regulation (EEC) No 2377/90 of 26 June 1990, as amended, Chevita GmbH submitted to the European Medicines Agency (the Agency) on 4 January 2007 an application for the extension of the entry in Annex II of Council Regulation (EEC) No 2377/90 for sodium salicylate with regard to oral use to include turkeys.

On 18 April 2007 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 to the Agency on 13 November 2007.

On 12 December 2007 the Committee for Medicinal Products for Veterinary Use adopted an opinion recommending the amendment of the existing entry in Annex II of Council Regulation (EEC) No 2377/90 for sodium salicylate with regard to oral use to include turkeys.

After having received the above mentioned opinion the European Commission returned it to the Committee requesting the revision of the opinion and the establishment of maximum residue limits.

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On 13 May 2008 the Committee for Medicinal Products for Veterinary Use confirmed its previous opinion recommending the amendment of the existing entry in Annex II of Council Regulation (EEC) No 2377/90 to include sodium salicylate for oral use to turkeys.

On 3 November 2009 the European Commission reiterated its request to the Committee to review its previous opinion and to propose the establishment of maximum residue limits for sodium salicylate in turkeys.

On 13 January 2010 the Committee adopted an opinion recommending the establishment of provisional maximum residue limits for sodium salicylate for oral use in turkeys, including a list of questions to be addressed by the applicant.

Commission Regulation (EU) No 914/2010[1] of 12 October 2010 established such provisional maximum residue limits.

The response to the list of questions further to the establishment of provisional maximum residue limits was submitted to the Agency on 11 November 2011.

Recommendation

The Committee, having considered the application and having evaluated the response to the list of questions, recommends by consensus the establishment of maximum residue limits for sodium salicylate in turkeys and the amendment of table 1 of the Annex to Commission Regulation (EU) No 37/2010, as follows:

Pharmaco-logically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions	Therapeutic classification
Sodium salicylate	Salicylic acid	Turkeys	400 µg/kg 2500 µg/kg 200 µg/kg 150 µg/kg	Muscle Skin and fat* Liver Kidney	Not for use in animals producing eggs for human consumption	Anti-inflammatory agents/Non steroidal anti-inflammatory agents

* Refers to fat and skin in natural proportions

[1] O.J. L269/5 of 13.10.2010

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 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, 9 February 2012

Signature on file

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

Annex I

European public MRL assessment report (EPMAR)