EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 April 2017
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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: EMEA/V/MRL/004706/FULL/0001

Name of the substance: Alarelin (INN)

Basis for the opinion

Pursuant to Article 3 of Regulation (EC) No 470/2009 of 6 May 2009, KUBUS S.A. submitted to the European Medicines Agency on 31 October 2016 an application for the establishment of maximum residue limits for alarelin in rabbits.

Recommendation

The Committee, having considered the application, recommends by consensus the establishment of maximum residue limits for alarelin in rabbits. Furthermore, and with reference to Article 5 of Regulation (EC) No 470/2009, the Committee agreed to extrapolate the maximum residue limits recommended in rabbits to all food producing species. Therefore, the Committee recommends by consensus the establishment of maximum residue limits for alarelin in accordance with the following table:

Pharmaco-logically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions	Therapeutic classification
Alarelin	NOT APPLICABLE	All food producing species	No MRL required	NOT APPLICABLE	NO ENTRY	Agents acting on the reproductive system

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

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 together with its appendices.

Annex I

European public MRL assessment report (EPMAR)