Veterinary Medicines Directorate

Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS
Telephone +44 (0)1932 336911

Post Authorisation Assessments

Trimediazine 15% Premix for Medicated Feeding Stuff

Vm 08007/4023

•	27 October 2020	Deletion of a non-significant specification parameter of the finished product.
•	02 May 2018	Change in the address of the marketing authorisation holder from Vetoquinol UK Limited, Vetoquinol House, Great Slade, Buckingham Industrial Park, Buckingham, MK18 1PA to Vetoquinol UK Limited, Steadings Barn, Pury Hill Business park, Nr. Alderton, Towcester, Northamptonshire, NN12 7LS.
•	06 December 2017	Addition of a manufacturer of the active substance or addition of a site of manufacture.
•	29 December 2016	Change to manufacturer responsible for batch release.
•	29 June 2016	Deletion of a manufacturing site for an active ingredient. Submission of an updated certificate of suitability. Submission of an updated certificate of suitability.
•	28 August 2014	Deletion of a non-significant specification parameter. Addition of a new specification parameter.
•	15 August 2014	Deletion of a manufacturer of the finished product and primary packaging site. Deletion of a site for control of the finished product. Deletion of secondary packaging site.
•	21 September 2012	Grouped variation to submit updated European Pharmacopoeia Certificates of Suitability for already approved active substance manufacturers. Deletion of an active substance manufacturer.
•	08 February 2012	Deletion of a non-significant specification parameter.
•	12 January 2011	Variation to amend the user safety warnings on the SPC and Product Literature.
•	27 October 2010	Submission of an updated European Pharmacopoeia Certificate of Suitability for an already approved active substance manufacturer.
•	16 March 2009	Variation to change the batch release arrangements and quality control testing of the finished product.
•	16 March 2009	Variation to change the batch release arrangements and quality control testing of the finished product.
•	17 February 2009	Variation to widen the tapped bulk density limits on the finished product.
•	20 January 2009	Submission of an updated European Pharmacopoeia Certificate of Suitability for an already approved active substance manufacturer.
•	14 November 2008	Deletion of a manufacturing site.
•	27 August 2008	Batch Control.

•	23 May 2007	Submission of a new European Pharmacopoeia Certificate of Suitability for a new active substance manufacturer.
•	27 April 2007	Renewal.
•	20 March 2007	Variation to update the SPC/Labelling in line with the Veterinary Regulations, 2005. Transfer of the legal category from MFS to POM-V.
•	06 March 2006	Submission of an updated European Pharmacopoeia Certificate of Suitability for an already approved active substance manufacturer.
•	23 February 2006	Submission of a new European Pharmacopoeia Certificate of Suitability for a new active substance manufacturer.
•	10 June 2005	Change in the specification of the Veterinary Medicinal Product.
•	20 May 2005	Change of the name of a manufacturer.
•	10 December 2004	Harmonisation of the SPC between the UK and IE.
•	10 December 2004	Variation to change the name and address of the Marketing Authorisation Holder and distributor.
•	27 May 2004	Addition of an active substance manufacturer.
•	30 January 2004	Change of site of testing for the finished product.
•	03 October 2003	Renewal.
•	31 March 2000	Addition of a non-sterile container.
•	24 May 1999	Variation concerning the active substance manufacturer.
•	07 February 1997	Variation to update the Licence Particulars.
•	03 September 1996	Change of the in-use shelf life.
•	26 June 1996	Change in the name and address of the PL/ATC Holder.
•	19 June 1996	Renewal.
•	29 April 1996	Addition of an active substance manufacturer.
•	07 April 1995	Addition of a target species.