Veterinary Medicines Directorate

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Post Authorisation Assessments

Trimediazine Plain Oral Powder

Vm 08007/4036

•	30 September 2022	Deletion of a manufacturer of the finished product.
•	06 May 2022	Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer.
•	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	Changes to a test procedure (including replacement or addition) for a starting material. Addition of a manufacturer of the active substance or addition of a site of manufacture.
•	21 July 2016	Addition of new manufacturing site (manufacture, control, release) Addition of new manufacturing site (manufacture, control, release) Addition of new manufacturing site (manufacture, control, release) Addition of new manufacturing site (manufacture, control, release) Addition of new manufacturing site (manufacture, control, 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.
•	05 April 2016	Deletion of a non-significant specification parameter.
•	21 September 2012	Grouped variation concerning the submission of updated European Pharmacopoeia Certificates of Suitability for already approved active substance manufacturers. Deletion of an active substance manufacturer.
•	08 February 2012	Deletions of a non-significant specification parameter.
•	17 November 2011	Change in the specification parameters.
•	27 October 2010	Submission of an updated European Pharmacopoeia Certificate of Suitability for already approved active substance manufacturer.
•	10 June 2009	Corrections to the SPC/Product Literature.
•	02 April 2009	Addition of test parameters for impurity testing and a change in the active substance specification.
•	27 March 2009	Variation to change the batch release arrangements and quality control testing of the finished product.

•	29 February 2008	Addition of an active substance manufacturer.
•	10 October 2007	Addition of an active substance manufacturer.
•	10 October 2007	Addition of an active substance manufacturer.
•	05 September 2007	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005. Transfer of the legal category from POM to POM-V.
•	22 February 2007	Renewal.
•	23 November 2005	Variation to change the address for the site of batch release.
•	30 September 2005	Variation to change the address of the Marketing Authorisation Holder and distributor.
•	27 September 2005	Harmonisation of the SPC with Ireland.
•	11 November 2004	Change of the horse withdrawal period in accordance with the horse passport legislation.
•	27 May 2004	Addition of an active substance manufacturer.
•	14 November 2003	Renewal.
•	25 February 2000	Change in the formulation of the finished product.
•	07 April 1999	Addition of a manufacturer and assembler of dosage form.
•	24 December 1997	Renewal.
•	07 February 1997	Update Licence Particulars.
•	17 June 1996	Change of the name and address of the PL/ATC Holder.
•	26 April 1996	Addition of an active substance manufacturer.