



Post Authorisation Assessments

Trimediazine Paste Oral Paste Vm 08007/4046

•	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.
•	03 November 2014	Addition of warning to Section 4.5 of the SPC "Not recommended in horses with known hypersensitivity, severe hepatic dysfunction or cardiac arrhythmias".
•	20 August 2013	Grouped variation to update European Pharmacopoeia Certificates of Suitability for already approved active substance manufacturers.
•	09 December 2009	Addition of a site of manufacture/assembly.
•	14 November 2008	Deletion of a manufacturer.
•	18 September 2008	Variation to change the batch release arrangements and quality control testing of the finished product.
•	03 July 2008	Variation to make changes to the horse withdrawal period.
•	20 December 2007	Renewal.
•	02 November 2007	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005. Transfer of the legal category from POM to POM-V.
•	26 May 2006	Addition of a secondary assembler.
•	25 April 2006	Change to the batch release arrangements.
•	19 August 2004	Change of address of the Marketing Authorisation Holder.
•	31 December 2003	Renewal.
•	30 January 2003	Addition of a pack type.
•	25 November 1998	Renewal.
•	07 February 1997	Variation to update the licence particulars.
•	28 June 1996	Change of company name.