Veterinary Medicines Directorate

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Post Authorisation Assessments

Tramazole 2.5% w/v SC Oral Suspension

Vm 11810/4007

•	05 May 2021	Removal of manufacture sites. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	12 April 2017	Submission of an updated Ph. Eur. certificate of suitability for an active substance manufacturer.
•	02 June 2016	To increase the shelf life of the finished product, as packaged for sale, from 2 years to 3 years. Change in the specification limits of the finished product
•	12 January 2016	Submission of a new or updated Ph. Eur. certificate of suitability.
•	07 February 2013	Grouped variation concerning the deletion of an in-process test, an increase of the finished product batch size, and a change to the finished product manufacturing process.
•	16 January 2013	Change to the test procedures for the finished product.
•	22 February 2012	Addition of an active substance manufacturer.
•	17 November 2010	Variation to replace a DMF with a CEP from an already approved active substance manufacturer.
•	15 January 2009	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005. Transfer of the legal category from PML to POM-VPS.
•	22 October 2008	Change in the name and address of an active substance manufacturer.
•	13 March 2006	Renewal.
•	31 March 2003	Renewal.
•	30 October 2002	Change of manufacturer/assembler of the finished product.
•	09 August 2002	Change of formulation of the finished product.
•	31 May 2002	Variation to change the name of the veterinary medicinal product.
•	05 June 2002	Variation to change the address of the Marketing Authorisation Holder.
•	02 May 2000	Variation to change the active substance manufacturer.
•	04 October 1996	Variation to change the address of the PL/ATC Holder.