



Post Authorisation Assessments

Soloxine 0.2 mg Tablet Vm 05653/4138

•	15 September 2016	Change of distributor details.
•	15 December 2011	Addition of an importer of final dosage form.
•	19 December 2007	Addition of a new importer of final dosage form.
•	22 November 2007	Addition of a quality control testing site.
•	22 November 2007	Addition of a quality control testing site.
•	10 September 2007	Addition of a site responsible for batch release.
•	03 May 2007	Variation to change the distributor.
•	07 March 2007	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005. Transfer of legal category from POM to POM-V.
•	19 January 2007	Variation to change the Marketing Authorisation Holder.
•	10 January 2007	Renewal.
•	06 June 2006	Harmonisation of the SPC.
•	13 December 2005	Variation to update a test procedure.
•	29 November 2005	Variation to change the manufacturing process.
•	24 August 2005	Variation to change the product name.
•	29 April 2005	Addition of an active substance manufacturer.
•	30 March 2005	Variation to change the formulation of the finished product.
•	30 March 2005	Variation to increase the batch size.
•	16 December 2004	Variation to change the specification of the finished product.
•	16 December 2004	Change to the markings on the tablet.
•	16 December 2004	Change to the manufacturer and assembler of the finished product.
•	18 December 2003	Variation to change Part II of the Dossier.
•	18 December 2003	Renewal.
•	10 August 1998	Change of importer.
•	26 June 1998	Change of Marketing Authorisation Holder.
•	10 February 1997	Renewal.