



Post Authorisation Assessments

Soloxine 0.8 mg Tablet

Vm 05653/4141

•	15 September 2016	Change in distributor details.
•	15 December 2011	Addition of an importer of final dosage form.
•	19 December 2007	Addition of an importer of final dosage form.
•	22 November 2007	Addition of a quality control testing site.
•	22 November 2011	Addition of a quality control testing site.
•	10 September 2007	Addition of a site responsible for batch release.
•	16 May 2007	Variation to change the distributor.
•	08 March 2007	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005. Transfer of the legal category from POM to POM-V.
•	24 January 2007	Variation to change the Marketing Authorisation Holder.
•	11 January 2007	Renewal.
•	06 June 2006	Harmonisation of the SPC.
•	14 December 2005	Variation to change 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	Change in the formulation of the finished product.
•	30 March 2005	Increase of batch size.
•	17 December 2004	Change to the manufacturer and assembler of the dosage form.
•	16 December 2004	Change to the markings on the tablets.
•	16 December 2004	Change in the specification of the finished product.
•	19 December 2003	Renewal.
•	18 December 2003	Variation to change Part II of the Dossier.
•	12 August 1998	Name change of the Importer.
•	26 June 1998	Change of Marketing Authorisation Holder.
•	12 February 1997	Transfer.