



Post Authorisation Assessments

Marbocyl SA 200mg Powder and Solvent for Solution for Injection Vm 08007/4079

•	12 October 2023	Changes to SPC sections 4.3, 4.5 and 4.6.
•	25 March 2022	Deletion of manufacturing site for an active substance. Changes to a test procedure for the active substance. Changes to a test for an intermediate. Extension of a re-test period/storage period of the active substance.
•	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.
•	10 November 2016	Addition of a new active substance manufacturing site. Change in the manufacturer of a starting material.
•	15 August 2014	Deletion of a secondary packaging site.
•	03 December 2008	Changes to the specification of the active substance
•	29 May 2008	Change of manufacturing site of the finished product
•	08 August 2007	Change of legal category from POM to POM-V Changes to the SPC and Product Literature to bring in line with new legislation
•	28 February 2006	Addition of a manufacturer of the active substance
•	04 March 2005	Renewal
•	22 October 2004	Change of manufacturer and assembler of the dosage form
•	10 September 2004	Change of address of the MAH
•	28 September 2001	Addition of a manufacturer of the active substance
•	28 March 2000	Additional presentation
•	06 October 1999	Addition of a manufacturer of the active substance