



Post Authorisation Assessments

Marbocyl P 5 mg Tablet Vm 08007/4109

•	29 September 2023	Addition of information for sections 4.3, 4.5 and 4.6 as a result of a PAR.
•	31 January 2023	Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product.
•	13 January 2023	Deletion of a non-significant in-process test during the manufacture of the finished product.
•	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.
•	23 March 2015	Changes to in-process tests applied during the manufacture of the finished product. Minor change in the manufacturing method of the finished product.
•	22 August 2013	Approval of previously unseen mock ups
•	08 February 2012	Addition of a new source of an excipient
•	03 December 2008	Changes to comply with Ph. Eur. Change to specification of the active substance
•	12 March 2008	Renewal
•	04 July 2007	Changes of legal category from POM to POM-V Changes to the SPC and Product Literature to bring in line with new legislation
•	27 February 2006	Addition of a manufacturer of the active substance
•	18 August 2004	Change of address of the MAH
•	12 February 2004	Minor change in manufacture of the finished product