

## Post Authorisation Assessments

### Marbocyl 10% Solution for Injection

Vm 08007/4149

•	21 September 2023	Changes in the SPC, labelling or package leaflet intended to implement the outcome of a procedure or recommendation from the competent authority or the Agency concerning risk management measures in pharmacovigilance related to veterinary medicinal products.
•	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.
•	31 August 2018	Change of MAH from Vetoquinol S.A., Magny-vernois, 70200 LURE, France to Vetoquinol UK Limited, Steadings Barn, Pury Hill Business Park, Nr Alderton, Towcester, Northants, NN12 7LS, United Kingdom.
•	22 May 2018	Change in distributor details. 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.
•	20 September 2016	Mock-ups approved.
•	15 June 2011	Change of withdrawal period for Meat from Pigs from 2 days to 4 days
•	22 February 2011	Additional batch size
•	03 December 2008	Changes to comply with Ph. Eur. Changes to the specification of the active substance
•	28 December 2007	Addition of a new type of packaging component
•	12 July 2007	Change of legal category from POM to POM-V Changes to the SPC and Product Literature to bring in line with new legislation
•	04 April 2007	Updates to the Dossier
•	06 November 2006	Renewal
•	28 February 2006	Addition of a manufacturer of the active substance
•	15 September 2005	Addition of a manufacturing site for packaging
•	25 February 2005	Renewal
•	17 December 2004	Change to test method performed on the finished product
•	19 November 2004	Change to test method performed on the active substance

•	31 March 2004	Batch control
•	05 January 2004	Change to a test method performed on the active substance
•	27 September 2001	Addition of a manufacturer of the active substance
•	28 July 2000	Addition of an indication for <i>E. coli</i> mastitis in Cattle
•	24 May 1999	Change to manufacturer of the active substance
•	24 February 1998	Change to shelf life (increase)