



## Post Authorisation Assessments

### Bayer Praziquantel 50 mg Tablets

Vm 08007/4153

•	04 August 2022	Change in manufacturing process of the finished product at Vetoquinol S.A.,Lure. Change in pack size outside the range of the currently approved pack size for the manufacturer Vetoquinol S.A.,Lure. Change to the specification parameters of the finished product. Changes to the in-process testing applied during manufacture of the finished product at Vetoquinol S.A.,Lure. Addition of manufacturing site for the finished product.
•	24 May 2022	Deletion of Ph. Eur. certificates of suitability for an active substance.
•	24 May 2022	Changes to a test procedure for the immediate packaging of the finished product. Increase in batch size of the finished product. Addition of a new specification parameter to the specification with its corresponding test method of the immediate packaging of the finished product. Addition of new tests and limits applied during the manufacture of the finished product. Deletion of an immediate packaging container. Minor change to an approved test procedure for the active substance. Minor change to an approved test procedure for the active substance. Addition of a manufacturer responsible for batch release including batch control/testing. Addition of a primary packaging site of the finished product. Addition of a secondary packaging site of the finished product.
•	19 May 2022	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	19 October 2021	Introduction of a new pharmacovigilance system.
•	05 November 2020	Change of MAH from Bayer Animal Health GmbH, 51368 Leverkusen, Germany to Vetoquinol UK Limited, Steadings Barn, Pury Hill Business Park, Nr. Alderton, Towcester, Northamptonshire, NN12 7LS.
•	09 June 2020	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already

		approved manufacturer. Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer.
•	09 June 2020	Change of MAH, from Bayer plc, 400 South Oak Way, Green Park, Reading, Berkshire, RG2 6AD to Bayer Animal Health GmbH, 51368 Leverkusen, Germany.
•	03 March 2020	Submission of a new Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	24 September 2019	Renewal
•	03 April 2019	Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer
•	18 September 2018	Change in distributor details from Bayer plc, Animal Health Division, Strawberry Hill, Newbury, Berkshire, RG14 1JA to Bayer plc, 400 South Oak Way, Green park, Reading, Berkshire, RG2 6AD.
•	05 May 2017	Change in the address of the marketing authorisation holder from Bayer plc, Animal Health Division, Bayer House, Strawberry Hill, Newbury, Berkshire, RG14 1JA to Bayer plc, 400 South Oak Way, Green Park, Reading Berkshire, RG2 6AD.