



Post Authorisation Assessments

Quantex 50 mg Tablets

Vm 08007/4173

•	04 August 2022	Change in test procedure for the immediate packaging of the finished product. Change in batch size of the finished product. Change in the specification parameters or limits of the immediate packaging of the finished product. Change to in-process tests or limits applied during the manufacture of the finished product. Deletion of one of the authorised immediate packaging components of the finished product. Minor changes to an approved test procedure for the active substance. Minor changes to an approved test procedure for the active substance. Addition of a manufacturer of the finished product. Additional primary packaging site for the finished product. Additional secondary packaging site for the finished product.
•	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.
•	25 May 2022	Deletion of Ph. Eur. certificates of suitability for an active substance.
•	17 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	Change of MAH, from Bayer plc, 400 South Oak Way, Green Park, Reading, Berkshire, RG2 6AD to Bayer Animal Health GmbH, 51368 Leverkusen, Germany.

•	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.
•	03 March 2020	Submission of a new Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	19 November 2019	Renewal - National
•	18 September 2018	Submission of a new Ph. Eur. certificate of suitability for an active substance excipient from a new manufacturer.
•	31 July 2018	Changes to the labelling and package leaflet.
•	21 June 2017	Change in local representative from CVS (UK) Ltd. to MiGroup.
•	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.