



Post Authorisation Assessments

Marfloquin 5 mg Tablets for Cats and Dogs

Vm 01656/4047

•	04 May 2024	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance. (NI) Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex. (NI)
•	20 March 2024	Change in the name or address or contact details of a qualified person for pharmacovigilance. (GB)
•	02 March 2023	New certificate of suitability from a new manufacturer.
•	21 February 2023	Change to comply with an update of the relevant monograph of the Ph. Eur. Change to comply with Ph. Eur. by removing reference to the internal test method and test method number.
•	17 January 2023	Change to comply with an update of the relevant monograph of the Ph. Eur. Change to comply with Ph. Eur. by removing reference to the internal test method and test method number.
•	01 July 2022	New certificate of suitability from a new manufacturer.
•	10 December 2020	Minor changes to an approved test procedure of the finished product. 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. Minor changes to an approved test procedure of the finished product. Addition of a manufacturing site of the finished product.
•	13 June 2019	Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	09 May 2019	Addition of a site where batch control takes place Deletion of manufacturing site for an active substance.
•	23 April 2018	Change in RMS from UK to ES.
•	21 February 2018	Renewal – UK as RMS
•	13 January 2017	Change to languages included on the mock-ups.
•	21 December 2016	Increase in the shelf life of the finished product from 2 years to 3 years.
•	20 July 2016	Extension of retest period for active substance.
•	20 May 2015	Change in manufacturing site of the active substance.
•	30 October 2014	Minor changes to test procedures of the finished product.

