



Post Authorisation Assessments

Bob Martin Clear Flea 57mg Tablets for Large Dogs Vm 00879/4059

•	23 February 2024	Deletion of a non-significant specification parameter for an excipient.
•	25 May 2023	Minor change to an approved test procedure for the finished product.
•	25 May 2023	Change in test procedure for the finished product: - Other changes to a test procedure.
•	21 December 2021	Deletion of a non-significant parameter of an active substance. Deletion of a non-significant parameter of an active substance.
•	13 May 2021	Change in the name of a manufacturer of the finished product, also responsible for batch release. Change in the address of the marketing authorisation holder from Elanco Europe Ltd, Lilly House, Priestley Road, Basingstoke, Hampshire, RG24 9NL to Elanco Europe Ltd, Form 2, Bartley Way, Bartley Wood Business Park, Hook, RG27 9XA, United Kingdom.
•	09 April 2021	Changes to the labelling and/or package leaflet. Change in distributor details. From Bob Martin (UK) Ltd to Pets Choice Ltd.
•	02 March 2021	Changes to a test procedure for the finished product.
•	11 May 2020	Minor change in the manufacturing process of the finished product. Addition of new tests and limits applied during the manufacture of the finished product.
•	09 December 2019	Change in shape or dimensions of the container or closure (immediate packaging).
•	05 June 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	07 March 2017	Introduction of a new pharmacovigilance system.
•	16 February 2017	To amend section 4.6 of the SPC and the related text in the product literature.
•	10 August 2016	Change in the name of a manufacturer of the finished product.
•	21 June 2016	Change in the legal entity from Novartis Animal Health UK Ltd to Elanco Europe Ltd.
•	02 June 2016	Deletion of a non-significant in-process test applied during the manufacture of the finished product. Change in the re-test period of the active substance.
•	12 June 2014	Changes to the test procedures and specification parameters for the active substance.
•	12 June 2014	Updates to test procedures and specification

		parameters for the finished product.
•	08 May 2014	Change in product name and approval of mock-ups.
•	05 February 2014	Renewal.
•	14 January 2014	Addition of a secondary packaging and batch release site.
•	13 November 2013	Addition of an alternative supplier of a starting material. Registration of a manufacturing process.
•	06 July 2011	Addition of a new specification parameter to a parameter of the starting material.
•	07 June 2011	Changes in the manufacturing process of the active substance.
•	07 June 2011	Changes in the manufacturing process of the active substance.
•	07 June 2011	Changes in the manufacturing process of the active substance.
•	22 September 2009	To update Part II of the dossier
•	08 July 2009	To increase the end of shelf life specifications.
•	02 July 2009	Change in test procedure of the finished product.