



Post Authorisation Assessments

Scalibor Protectorband 1.0 g Medicated Collar for Large Sized Dogs Vm 01708/3012

•	04 March 2024	Deletion of a test procedure for an excipient. Deletion of a non-significant specification parameter of an excipient.
•	21 July 2023	One-off alignment of the product information with version 9.0* of the QRD templates.
•	20 February 2023	Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product. Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product.
•	16 March 2022	Minor changes to an approved test procedure of the finished product.
•	05 October 2020	Change in the specification limits of an excipient.
•	01 October 2020	Changes to the labelling and package leaflet.
•	14 August 2020	Change in the name of the marketing authorisation holder from Intervet UK Limited to MSD Animal Health UK Limited.
•	22 April 2020	Updates to the SPC following a Repeat Use procedure.
•	16 January 2020	Change in the name and address of the manufacturer of the finished product. Change in the name of the manufacturer of the finished product.
•	16 January 2020	Minor changes to an approved test procedure of the finished product.
•	13 November 2018	Change in the safety database of an existing pharmacovigilance system as described in the DDPS
•	07 March 2018	Change in the name of a manufacturer of the active substance. Change in the name of an ASMF holder.
•	05 January 2017	Changes to a DDPS following the assessment of the same DDPS in relation to another medicinal product of the same MAH.
•	28 September 2016	Update to layout and branding style of Mock-ups.
•	06 September 2016	Change in the name of the supplier of a starting material used in the manufacture of the active substance. Addition of two manufacturers of an intermediate used in the manufacturing process of the active substance.
•	22 July 2015	Deletion of non-significant in-process tests applied during the manufacture of the finished product.
•	07 May 2015	Change in the name of the manufacturer of the active

		substance.
•	01 April 2015	Changes to section 4.6 of the SPC.
•	28 November 2014	Update to the DDPS.
•	20 November 2013	Repeat Use Comment.
•	21 August 2013	Deletion of a manufacturing site.
•	14 February 2013	Variation to update the Active Substance Master File.
•	13 November 2012	Variation to update the ERA, in preparation of submitting a future repeat use application.
•	18 July 2012	Variation to harmonise the specifications for a non-pharmacopoeial excipient.
•	15 June 2011	Variation to add an additional manufacturing site for secondary packaging.
•	04 May 2010	Variation to change the legal category from POM-V to NFA-VPS.
•	19 April 2010	Variation to make changes to the label text on the small immediate packaging units.
•	31 March 2010	Variation to increase the batch size from 100kg to 300kg
•	26 March 2010	Renewal UK as CMS.
•	09 June 2009	Add SGS Life Science Services, France, as an additional site for finished product testing.
•	05 December 2008	Increase the batch size from 50 kg to 100 kg.
•	03 March 2006	Amendment to dossier.
•	16 August 2005	Add a source of the active substance.
•	07 September 2004	Renewal procedure.
•	11 April 2004	Change TSE status.
•	18 February 2004	Change to sachet text layout.
•	09 May 2003	Addition of a site for packaging and release.