Veterinary Medicines Directorate

Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS
Telephone +44 (0)1932 336911

Post Authorisation Assessments

Scalibor Protectorband 0.76 g medicated Collar for Small and Medium Sized Dogs

Vm 01708/5078

•	25 March 2024	Minor change in the manufacturing process. Change to in-process tests or limits.
•	11 September 2023	Minor changes: – to an approved test procedure, for a starting material, reagent or intermediate used in the manufacturing process of the active substance, or for an excipient.
•	21 July 2023	One-off alignment of the product information with version 9.0* of the QRD templates.
•	05 May 2023	Deletion of a test procedure for the finished product.
•	04 May 2023	Deletion of a non-significant specification parameter of an excipient.
•	30 December 2022	Minor change in the manufacturing process. Minor change in the manufacturing process.
•	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.
•	05 February 2014	Update to SPC and packaging with changes agreed in repeat use procedure.
•	20 November 2013	Repeat use procedure.
•	21 August 2013	Deletion of an active substance manufacturing site.
•	14 February 2013	Changes to the manufacturing process for the active substance.
•	13 November 2012	Submission of an updated ERA.
•	18 July 2012	Change in the specification of an excipient.
•	15 June 2011	Addition of a secondary packaging site.
•	04 May 2010	Change of legal category from POM-V to NFA-VPS.
•	19 April 2010	Changes made to the product literature.
•	31 March 2010	Increase batch size of the finished product.
•	26 March 2010	Renewal.
•	09 June 2009	Addition of a finished product manufacturer responsible for batch release and quality control.
•	09 June 2009	Addition of a manufacturer responsible for primary and secondary packaging.
•	05 December 2008	Change in batch size.
•	03 March 2006	Addition of a new therapeutic indication.
•	16 August 2005	Addition of an active substance manufacturing site.
•	07 September 2004	Renewal.
•	11 April 2004	Change of TSE format from Format 3 to Format 2.
•	18 February 2004	Updates to the SPC and product literature.
•	09 May 2003	Addition of a new site for packaging and batch release.