Veterinary Medicines Directorate

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

Post Authorisation Assessments

Milbemax 12.5 mg/125 mg chewable tablets for dogs

Vm 00879/3028

•	13 April 2024	One-off alignment of the product information with version 9.0* of the QRD templates.
•	04 February 2022	Deletion of manufacturing site for an active substance.
•	14 October 2021	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	11 February 2021	Addition of a new specification parameter with its corresponding test method of a reagent used in the manufacturing process of the active substance. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	02 February 2021	Addition of a secondary packaging site of the finished product. Addition of a primary packaging site of the finished product.
•	28 September 2020	Minor changes to an approved test procedure of the finished product. Minor changes to an approved test procedure of the finished product. Minor changes to an approved test procedure of the finished product.
•	16 September 2020	Change in the address of the Marketing Authorisation Holder from Elanco Europe Ltd, Lilly House, Priestley Road, Basingstoke, Hampshire, RG24 9NL, United Kingdom to Elanco Europe Ltd, Form 2, Bartley Way, Bartley Wood Business Park, Hook, RG27 9XA, United Kingdom.
•	10 December 2019	Minor changes to an approved test procedure of the finished product. Minor changes to an approved test procedure of the finished product. Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State.
•	05 June 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	29 May 2019	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved

		manufacturer. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	29 January 2019	Change in the address of a manufacturer used in the manufacture of the active substance.
•	04 October 2018	Change of specifications of a former non Pharmacopoeial active substance to comply with the Ph. Eur.
•	27 September 2018	Change in the SPC, Labelling or Package Leaflet of veterinary medicinal products intended to implement the outcome of a procedure concerning PSUR.
•	14 August 2017	Addition of a new specification parameter with its corresponding test method of an active substance used in the manufacturing process of the active substance Changes to a test procedure (including replacement or addition) for the active substance Introduction of a new site of manufacture Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer
•	21 June 2017	Change in batch size (including batch size ranges) of active substance used in the manufacturing process of the active substance Change in the specification parameters or limits of an active substance
•	07 March 2017	Introduction of a new pharmacovigilance system.
•	15 August 2016	Change in the name of a manufacturer of the finished product including manufacturer responsible for batch release.
•	06 July 2016	Change in the name of the Marketing Authorisation Holder from Novartis Santé Animale to Elanco France in France and Poland only.
•	06 July 2016	Change in the name and address of the Marketing Authorisation Holder in Spain and Italy only.
•	16 March 2016	Change in distributor details Change in legal entity
•	09 April 2015	Changes in the specification parameters and limits of the finished product.
•	18 February 2015	Change in the packaging material of the bulk product. Change in holding time of the bulk product. Change in the test method of an in-process-control.
•	28 August 2014	Approval of mock-ups.
•	30 April 2014	Changes to an existing pharmacovigilance system as described in the DDPS.
•	27 March 2014	Submission of updated Ph. Eur. Certificates of Suitability.
•	07 February 2014	Change in MAH address.
•	18 July 2013	Change in address of manufacturer/supplier of reagent used in the manufacture of the active substance. Change in the manufacturing process of the active substance. Change of in process limits applied during manufacture of the active substance. Change to in process tests applied during the manufacture of the active substance. Change in specification limits of a reagent involved in the

		manufacture of the active substance. Minor amendments to part 2 of the dossier. Inclusion of restricted part of ASMF in part 2 of the dossier.
•	05 July 2013	To change the address of the MAH in Denmark, Finland, Norway and Sweden and corrections to the address of the MAH in Cyprus.
•	25 June 2013	Addition of new therapeutic indications.
•	28 March 2013	To change the address of the marketing authorisation holder (MAH) in France only.
•	12 November 2012	Changes to the DDPS that do not impact on the operation of the pharmacovigilance system Addition of a primary packaging site and a secondary packaging site.
•	18 April 2011	Submission of 2 new or updated Ph. Eur. Certificates of Suitability.
•	06 August 2010	To change the name and contact details of the qualified person for pharmacovigilance.
•	6 August 2010	Changes to an existing pharmacovigilance system.
•	29 February 2008	Deletion of a manufacturing site. Renewal.
•	5 November 2007	Change of name/ address of manufacturer of the active substance.
•	3 October 2007	Change in the name and/ or address of the Marketing Authorisation Holder.
•	15 January 2007	Changes to the SPC.
•	6 February 2006	Addition of new therapeutic indications.
•	7 January 2006	New indications.
•	26 May 2005	Repeat use procedure.
•	08 November 2004	Change to the name of a supplier of the active substance.
•	06 August 2004	Minor change in the manufacture of the finished product.
•	29 March 2004	Addition of a new pack size.