Veterinary Medicines Directorate

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Post Authorisation Assessments

Milbemax 12.5 mg/125 mg chewable tablets for dogs

Vm 00879/3027

•	13 April 2024	One-off alignment of the product information with version 9.0* of the QRD templates.
•	14 September 2022	Change in the specification limits of the finished product.
•	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.
•	04 April 2019	Minor change to an approved test procedure for an excipient. Minor change to an approved test procedure for an excipient. Minor change in the manufacturing process 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. Addition of an alternative site of an excipient. Addition of a manufacturing site of the finished product.
•	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.
•	20 February 2018	Change in the specification limits of the finished product. Change in the specification limits of the finished product.
•	24 August 2017	Addition of a supplier of packaging components or devices
•	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 February 2017	Minor change in the manufacturing process. Addition of a manufacturing site of the finished product.
•	06 September 2016	Minor changes to sections 4.4 & 4.8 of the SPC.
•	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
•	15 September 2015	Change in the immediate packaging of the finished

		product.
•	24 July 2015	Submission of an updated TSE Certificate of Suitability.
•	02 May 2015	To add a new pack size for the finished product.
•	02 March 2015	Minor changes to sections 4.2 and 4.8 of the SPC.
•	05 November 2014	Renewal.
•	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.
•	16 January 2013	To reduce the shelf life of the finished product as packaged for sale from 3 years to 2 year.
•	12 November 2011	Changes to the DDPS that do not impact on the operation of the pharmacovigilance system.
•	30 August 2012	Variation to change the manufacturer of the tablets.
•	15 February 2012	Changes to the dimensions of the artwork.
•	07 September 2011	To change the immediate packaging of the finished product.
•	11 July 2011	Grouped variation to introduce the batch size range from 100 kg to 500 kg and to make minor changes to the manufacturing process.
•	18 April 2011	Grouped variation to add an additional manufacturer of the active substance and also to submit an updated Ph. Eur. certificate of suitability for approved manufacturer.
•	06 August 2010	Grouped variation to add primary and secondary packaging sites.
•	06 August 2010	Grouped variation to change the name and contact details of the qualified person for pharmacovigilance.