



Post Authorisation Assessments

Malaseb Shampoo for Dogs and Cats Vm 24883/4005

•	07 August 2023	Change in the specification parameters and/or limits of an excipient.
•	08 February 2023	Updated certificate of suitability from an already approved manufacturer.
•	20 December 2022	Editorial changes to part 2 of the dossier. Editorial changes to part 2 of the dossier. Editorial changes to part 2 of the dossier.
•	03 August 2022	Addition of a site for microbiological testing for the finished product.
•	28 July 2022	Updated certificate of suitability from an already approved manufacturer.
•	15 February 2022	Minor changes to an approved test procedure of the finished product.
•	23 September 2021	Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer.
•	16 December 2020	Minor change to an approved test procedure for an excipient.
•	02 April 2020	Submission of a new Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	25 July 2019	Addition of a manufacturer responsible for batch release including batch control/testing.
•	12 February 2019	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	01 August 2018	Change in RMS from UK to IE.
•	10 April 2018	Repeat Use application to add 2 new member states
•	03 August 2017	Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer
•	01 May 2015	Changes to the labelling.
•	06 March 2015	To change the batch size of the finished product.
•	16 January 2014	To change the named local representative for the product in Belgium only.
•	10 October 2013	Changes to the composition (excipients) of the finished product.
•	10 October 2013	Change of manufacturing site for the finished product and batch release.

•	28 August 2013	Renewal procedure – UK as RMS.
•	29 November 2012	To widen the finished product shelf life specification for an active substance.
•	02 November 2012	Addition of a site where batch control/testing takes place.
•	02 November 2012	Change in the address of a manufacturer of the finished product.
•	20 July 2012	Submission of an updated Ph. Eur certificate of suitability for an active substance from and already approved manufacturer.
•	20 July 2012	Submission of revised drawings for the primary packaging specifications.
•	18 February 2011	Changes to an existing pharmacovigilance system as described in the DDPS.
•	15 December 2010	To change the distributor.
•	26 May 2010	Update of SPC, packaging and labelling.
•	05 March 2010	Repeat use MA
•	09 March 2009	Change of MAH name/address
•	17 December 2008	To change the distributor
•	05 March 2008	Corrections/simple text layout changes to SPC and/or product literature
•	05 March 2008	Corrections/simple text layout changes to SPC and/or product literature
•	28 December 2007	Product name change from Sebolyse Shampoo for Dogs and Cats, to Malaseb Shampoo.
•	19 December 2007	Change in test procedure for an excipient