

Post Authorisation Assessments

Malaseb Shampoo for Dogs and Cats Vm 24883/4005

16 February 2026	Change to comply with Ph. Eur. for the active substances. (NI)
02 February 2026	Submission of an updated Ph. Eur. CEP for an active substance. (NI)
28 November 2025	Submission of an updated Ph. Eur. CEP for an active substance. (GB)
31 July 2025	Alignment of the product information with version 9.0* of the EU QRD templates.
15 April 2025	Change to quality testing arrangements for the finished product. (GB)
19 January 2025	Update to a Ph. Eur. CEP for an already authorised manufacturer of the active substance. (NI)
14 December 2024	Update to a Ph. Eur. CEP for an already authorised manufacturer of the active substance. (GB)
25 June 2024	Change to in process tests applied during manufacture of the finished product.
12 January 2024	Change to comply with Ph. Eur. for the active substances. (GB)
27 November 2023	Minor changes to an approved test procedure for the finished product (GB).
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