



Post Authorisation Assessments

Ventipulmin Syrup 25 micrograms/ml Vm 08327/5059

02 September 2024	Deletion of a manufacturing site for an active substance.
19 July 2023	Change in dimensions of the container or closure of a non-sterile finished product - Bottle dimensions. Change in dimensions of the container or closure of a non-sterile finished product - Cap dimensions. Change in dimensions of the container or closure of a non-sterile finished product - Editorial changes to dossier.
13 April 2023	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).
18 January 2021	Change in the name of a manufacturer of the finished product.
05 August 2020	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
09 November 2018	Change of MAH, from Boehringer Ingelheim Ltd, Ellesfield Avenue, Bracknell, Berkshire, RG12 8YS to Boehringer Ingelheim Animal Health UK Ltd, Ellesfield Avenue, Bracknell, Berkshire, RG12 8YS.
22 August 2018	Change in test procedure for the finished product. Change in test procedure for the finished product. Change in test procedure for the finished product.
16 January 2018	Submission of a new Ph. Eur. certificate of suitability for an active substance excipient from a new manufacturer. Introduction of a re-test period of the active substance.
13 January 2017	Variation to harmonise the SPC and product literature with Ireland.
16 September 2015	Submission of an updated certificate of suitability.
04 December 2014	Addition of statement to Section 4.11 of the SPC "Do not use in animals producing milk for human consumption."
13 September 2013	Grouped variation to update the testing procedures (testing parameters/limits/procedures). Update to the manufacturing specification to correct a typographical error.
28 June 2013	Deletion of a manufacturer.
09 February 2012	Deletion of a manufacturer of the active substance, finished product, and assembler.
11 May 2011	Submission of an updated European Pharmacopoeia Certificate of Suitability for an already approved active substance manufacturer.
22 December 2010	Variation to make changes to section 4.10 of the SPC.

02 November 2010	Variation to change the qualitative composition of a packaging component.
02 November 2010	Variation to change the qualitative composition of a packaging component.
02 November 2010	Addition of a manufacturer.
02 November 2010	Addition of a manufacturer responsible for primary packaging.
26 October 2010	Addition of a manufacturer responsible for secondary packaging and product shipping.
29 July 2008	Variation to implement minor changes (UK only) to bring the labelling in line with a recent IE Renewal.
12 March 2008	Submission of a new or updated European Pharmacopoeia Certificate of Suitability for a new or existing manufacturer.
16 January 2008	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005. Transfer of the legal category from POM to POM-V.
22 November 2007	Variation to widen the viscosity limits for the release and shelf life.
07 March 2007	Variation to change the batch release arrangements and quality control testing of the finished product.
15 November 2005	Renewal.
27 September 2005	Variation to replace the current HPLC methods and TLC methods with a new HPLC method to widen viscosity limits.
17 November 2004	Variation to change the importer.
16 July 2004	Variation to change the text on the bottle and carton only.
08 April 2004	Reduction of shelf life.
30 January 2004	Addition of a site of secondary assembly.
05 January 2004	Amendments of packaging insert.
01 July 2003	Change of material for two packaging components.
01 July 2003	Variation to make minor changes to the manufacturing process.
30 April 2003	Variation to change the name of a manufacturer and assembler.
28 March 2002	Change of horse withdrawal period.
07 November 2001	Change of manufacturer of the active substance.
11 October 2001	Change of manufacturer of the active substance.
27 July 2001	Change of active substance specification.
28 February 2000	Change of manufacturer of the active substance.
21 December 2000	Renewal.
26 October 1998	Addition of a manufacturer.
31 July 1997	Variation concerning the manufacturer of dosage form.
31 July 1997	Change of name of a manufacturer/assembler.
31 July 1997	Addition of a secondary assembler of dosage form.
09 July 1997	Deletion of a target species.
09 July 1997	Change in the testing specifications (packaging).
03 October 1996	Renewal.