Veterinary Medicines Directorate

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Post Authorisation Assessments

Ventipulmin Syrup 25 micrograms/ml

Vm 08327/4310

•	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.