Veterinary Medicines Directorate

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Post Authorisation Assessments

Ventipulmin Granules 16 micrograms/gram

Vm 08327/4308

•	15 August 2023	Change in shape and dimensions of the container for the finished product. Change in shape and dimensions of the closure for the finished product.
•	06 April 2023	Change in the name or address or contact details of a qualified person for pharmacovigilance.
•	05 August 2020	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	21 August 2019	Change in the specification parameters and limits of an excipient.
•	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.
•	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.
•	18 December 2015	Correct the cap description and update the relevant Container Closure documents.
•	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.”
•	09 September 2013	Variation to Delete manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier).
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•	09 September 2013	Variation to Delete manufacturing sites for an active

		substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier).
•	27 June 2012	Grouped variation to update test methods used during testing of the finished product.
•	01 March 2012	Grouped Variation to remove a site of assembly.
•	09 February 2012	Deletion of a site responsible for finished product manufacture, active substance manufacture, and assembly.
•	20 April 2011	Submission of an updated European Pharmacopoeia Certificate of Suitability for an already approved active substance manufacturer.
•	19 April 2011	Variation to make a change to the finished product test procedure.
•	22 December 2010	Variation to make changes to section 4.10 of the SPC.
•	13 October 2010	Reduction of shelf life of the finished product.
•	09 June 2010	Addition of a test to the testing specification.
•	10 March 2010	Addition of a test parameter to the excipient specification.
•	19 March 2009	Renewal.
•	14 May 2008	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005. Transfer of the legal category from POM to POM-V.
•	12 March 2008	Submission of an updated European Pharmacopoeia Certificate of Suitability for an already approved active substance manufacturer.
•	22 September 2005	Change to comply with the European Pharmacopoeia.
•	20 October 2004	Renewal.
•	22 August 2003	Variation to change the product testing specification.
•	22 August 2003	Addition of a manufacturer responsible for dosage form, assembly, and release.
•	22 August 2003	Addition of a batch size.
•	02 June 2003	Variation to change the name of the manufacturer of dosage form.
•	30 April 2003	Variation to change the name of the manufacturer and assembler of dosage form.
•	28 March 2002	Variation to change the horse withdrawal period.
•	16 October 1991	Addition of an active substance manufacturer.
•	11 October 2001	Change to the active substance specification.
•	04 July 2001	Renewal.
•	07 January 2000	Addition of a site responsible for assembly of dosage form.
•	26 October 1998	Name change of a manufacturer/assembler.
•	31 July 1997	Addition of a secondary assembler.
•	31 July 1997	Addition of a secondary assembler.
•	31 July 1997	Addition of a secondary assembler.
•	09 July 1997	Deletion of a target species.