Veterinary Medicines Directorate

Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS
Telephone +44 (0)1932 336911

Post Authorisation Assessments

Ventipulmin Solution for Injection 30 micrograms/ml

Vm 08327/4309

•	14 April 2023	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).
•	20 April 2022	Deletion of manufacturing site for an active substance.
•	05 August 2020	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	21 April 2020	Changes to the labelling and package leaflet.
•	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.
•	02 August 2017	Addition of a site where batch control/testing takes place Addition of a site where batch control/testing takes place
•	20 July 2016	Addition of a QC site for the finished product.
•	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).
•	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).
•	26 April 2013	Grouped variation concerning the: increase of the batch size of the finished product, addition of a test method used in the finished product manufacturing process, and the replacement of two existing test methods.
•	09 November 2012	Addition of a specification parameter for a packaging component.
•	04 September 2012	Grouped variation concerning the deletion of an existing test limit, the addition of a test method, and to update the specifications for active substance decomposition.

•	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.
•	11 May 2011	Submission of an updated European Pharmacopoeia Certificate of Suitability for an already approved active substance manufacturer.
•	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.
•	29 April 2004	Variation to reduce the shelf life of the finished product.
•	09 March 2004	Variation to permit shared labelling between the IE and UK.
•	02 December 2003	Change of package insert.
•	25 June 2003	Change of name of the Marketing Authorisation Holder.
•	28 March 2002	Variation to change the horse withdrawal period.
•	16 October 1991	Addition of an active substance manufacturer.
•	15 October 2001	Change to the active substance specification.
•	04 April 2000	Change of name of a manufacturer.
•	20 October 1999	Renewal.
•	26 October 1998	Variation to change the active ingredient specification.
•	31 July 1997	Variation to change the name of a manufacturer/assembler.
•	31 July 1997	Variation to change the name of a manufacturer/assembler.
•	31 July 1997	Addition of a secondary assembler.
•	09 July 1997	Deletion of a target species.
•	11 September 1996	Addition of a manufacturer/assembler of dosage form.
•	04 September 1996	Variation concerning the manufacturing site of dosage form.