Veterinary Medicines Directorate

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

Post Authorisation Assessments

Flubenol 5% w/w Oral Powder for Pigs

Vm 00879/4183

•	25 January 2024	Deletion of a packaging site for the finished product.
•	30 October 2023	Deletion of a manufacturing site responsible for manufacturing, primary packaging, secondary packaging, labelling, QC & stability testing and QP batch release.
•	18 January 2023	Submission of an updated certificate of suitability.
•	01 September 2022	Addition of a batch release site for the finished product. Addition of a batch release site for the finished product. Addition of a manufacturing site of the finished product.
•	01 September 2022	Additional site for QC testing of the finished product. Additional site for QC testing of the finished product. Additional site for QC and stability testing of the finished product. Deletion of a non-significant specification parameter of the finished product.
•	11 June 2021	Addition of a secondary packaging site of the finished product. Addition of a primary packaging site of the finished product.
•	01 October 2020	Change of Marketing Authorisation Holder from Eli Lilly and Company Limited, Lilly House, Priestley Road, Basingstoke, Hampshire, RG24 9NL to Elanco Europe Ltd, Form 2, Bartley Way, Bartley Wood Business Park, Hook, RG27 9XA, United Kingdom.
•	05 June 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	10 May 2018	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	09 April 2015	Submission of an updated certificate of suitability.
•	14 March 2013	Amendments to the SPC and Product Literature
•	20 June 2012	Change of MAH
•	21 March 2012	Change in specification of the active substance Submission of an updated Ph. Eur. Certificate of Suitability for an active substance from an already approved manufacturer
•	07 March 2012	Change of distributor
•	26 April 2011	Introduction of a retest period of 60 months and storage conditions of 'Do not store above 30˚C' for the active substance
•	16 February 2011	Submission of 2 updated Ph. Eur. Certificates of Suitability for an active substance from an already

		approved manufacturer
•	16 February 2010	Addition of a manufacturer of the active substance
•	30 January 2010	Deletion of an assembler of the dosage form
•	07 April 2009	Harmonisation of the SPC
•	06 March 2008	Replacement of two manufacturing sites for the finished product
•	27 February 2008	Change of address of the MAH
•	23 January 2008	Change of legal category from MFX to POM-VPS Changes to the SPC and Product Literature to bring in line with new legislation Addition of an indication against *Strongyloides ransomi*
•	02 November 2007	Replacement of the two manufacturing sites of the finished product
•	09 October 2007	Change in batch size of the finished product
•	30 November 2006	Minor change in the manufacturing process of the finished product
•	18 September 2006	Submission of a new Ph. Eur. Certificate of Suitability for an active substance
•	05 July 2006	Change of in-process controls implemented during the manufacture of the finished product Change of specification for the finished product Change in manufacturing process of the finished product
•	21 June 2006	Renewal
•	05 June 2006	Change in batch size of the finished product Change of address of the manufacturer and assembler of the dosage form
•	17 March 2006	Change in composition of the packaging
•	27 July 2005	Submission of a Ph. Eur. Certificate of Suitability for an active substance
•	18 March 2004	Change of dosage particulars